

MT LEGISLATIVE HISTORY

Chapter 403 1977

Bill (H) 286 S _____

Original bill & hist. ✓ C

H. Committee on Public Health, Welfare & Safety S. Committee on Public Health, Welfare & Safety

Hearing Date(s) FEB 22 ✓ C

Hearing Date(s) MAR 29 ✓ C

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MAR 31 ✓ C

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Date Out _____ C

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Did this bill originate in an interim committee? ____ Yes ____ No

Committee _____

Report _____

THE LAW LIBRARY WAS NOT PROVIDED WITH MINUTES FOR PROBLEMS OF THE ELDERLY SUBCOMMITTEE.
THE HISTORICAL SOCIETY ARCHIVES MAY HAVE BEEN GIVEN THEM AS PART OF THE ORIGINAL SET. CON-
TACT THEM AT 406-444-2681.

1 H BILL NO. 286
2 INTRODUCED BY RAIMER James Kessler Conroy

3
4 A BILL FOR AN ACT ENTITLED: "AN ACT TO BE CALLED THE
5 MONTANA DRUG PRODUCT SELECTION ACT, ALLOWING FOR PRODUCT
6 SELECTION OF CERTAIN PRESCRIBED DRUGS; AMENDING SECTIONS
7 27-703 AND 66-1523, R.C.M. 1947."

8
9 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

10 Section 1. Short title. This act may be cited as the
11 "Montana Drug Product Selection Act".

12 Section 2. Definitions. As used in this act the
13 following definitions apply:

14 (1) "Bioavailability" means the extent and rate of
15 absorption from a dosage form as reflected by the
16 time-concentration curve of the administered drug in the
17 systemic circulation.

18 (2) "Bioequivalent" means a chemical equivalent which,
19 when administered to the same individual in the same dosage
20 regimen, will result in comparable bioavailability.

21 (3) "Brand name" means the proprietary or the
22 registered trademark name given to a drug product by its
23 manufacturer, labeler, or distributor and placed upon the
24 drug, its container, label, or wrapping at the time of
25 packaging.

1 (4) "Chemical equivalent" means drug products that
2 contain the same amounts of the same therapeutically active
3 ingredients in the same dosage forms and that meet present
4 compendium standards.

5 (5) "Drug product" means a dosage form containing one
6 or more active therapeutic ingredients along with other
7 substances included during the manufacturing process.

8 (6) "Generic name" means the chemical or established
9 name of a drug product or drug ingredients published in the
10 latest edition of the official United States Pharmacopoeia
11 or official Homeopathic Pharmacopoeia of the United States.

12 (7) "Present compendium standard" means the official
13 standard for drug excipients and drug products listed in the
14 latest revision of the United States Pharmacopoeia and the
15 National Formulary.

16 (8) "Prescriber" means a practitioner licensed under
17 the professional laws of the state to administer medicine
18 and drugs.

19 (9) "Product selection" means to dispense without the
20 prescriber's express authorization a different drug product
21 in place of the drug product prescribed.

22 (10) "Therapeutically equivalent" means those chemical
23 equivalents which, when administered in the same dosage
24 regimen, will provide essentially the same therapeutic
25 effect as measured by the control of a symptom or a disease

INTRODUCED BILL

1 and/or toxicity.

2 Section 3. Product selection permitted. (1) Except as
3 limited by subsection (2) of this section and unless
4 instructed otherwise by the purchaser, the pharmacist who
5 receives a written or oral prescription for a specific drug
6 product by brand or proprietary name may select an equally
7 priced or less expensive drug product with the same generic
8 name, the same strength, quantity, dose, and dosage form as
9 the prescribed drug which is, in the pharmacist's
10 professional opinion, therapeutically equivalent.

11 (2) If, in the professional opinion of the prescriber,
12 it is medically necessary for his patient that an equivalent
13 drug product not be selected, the prescriber may so indicate
14 by certifying in his own handwriting that in his
15 professional judgment the specific brand name drug product
16 is medically necessary for that particular patient. An
17 example of an acceptable certification would be the notation
18 "medically necessary" or words of similar meaning on the
19 face of a written prescription. In no case may a facsimile
20 of the handwritten signature be preprinted to indicate
21 "medically necessary". In the case of a prescription
22 transmitted orally, the prescriber must expressly indicate
23 to the pharmacist that the brand name drug product
24 prescribed is medically necessary.

25 Section 4. Notice to purchaser. (1) A pharmacist who

1 selects a drug product as provided in [section 3] shall
2 notify the person presenting the prescription of the product
3 selection, together with the existence and amount of the
4 retail price difference between the brand name drug product
5 and the drug product substituted for it and shall inform the
6 person presenting the prescription that he may refuse the
7 product selection as provided in [section 3].

8 (2) Each pharmacy shall display in a prominent place
9 that is in clear and unobstructed public view, at or near
10 the place where prescriptions are dispensed, a sign stating,
11 "This pharmacy may be able to select a less expensive drug
12 product which is therapeutically equivalent to the one
13 prescribed by your physician unless you or your physician
14 request otherwise." The printing on the sign shall be in
15 block letters not less than 1 inch in height.

16 Section 5. Product selection when no increased cost.

17 (1) A pharmacist may select a drug product under [section
18 3] only when there will be a savings or no increased cost to
19 the purchaser.

20 (2) A pharmacist selecting a less expensive drug
21 product must pass on to the purchaser the full amount of the
22 savings realized by the product selection. In no event may
23 the pharmacist charge a different professional fee for
24 dispensing a different drug product than the drug product
25 originally prescribed.

(3) If the prescriber prescribes a drug product by its generic name, the pharmacist must, consistent with reasonable judgment, dispense the lowest retail priced, therapeutically equivalent brand which is in stock.

Section 6. Records required and labeling. (1) Each pharmacist shall maintain a record of any product selection of a generically equivalent drug product for a prescribed brand name drug product as provided for in this act.

(2) Except as provided in subsection (3) of this section, when a pharmacist dispenses a selected drug product as authorized, he must label the prescription container with the name of the dispensed drug product. If the dispensed drug product does not have a brand name, the prescription label must indicate the generic name of the drug product dispensed along with the name of the drug product's manufacturer.

(3) Unless the prescriber writes "do not label" or words of similar meaning on the prescription or so designates in an oral transmission of the prescription, a prescription dispensed by a pharmacist must bear upon the label the name of the medication in the container.

Section 7. Product selection not practice of medicine. The selection of a drug product by a registered pharmacist under the provisions of this act does not constitute the practice of medicine.

Section 8. When product selection evidence of negligence. (1) A pharmacist making a product selection under the provisions of this act assumes no greater responsibility for selecting the dispensed drug product than he would incur in filling a prescription for a drug product prescribed by a generic name.

(2) In no event when a pharmacist selects a drug product will the prescriber be liable in an action for loss, damage, injury, or death to a person caused by the use of the selected drug product unless the original drug product was incorrectly prescribed.

Section 9. Rule making authorized. The board of pharmacists may adopt, amend, or repeal rules necessary for the implementation, continuation, and enforcement of this act in accordance with the Montana Administrative Procedure Act.

Section 10. Section 27-703, R.C.M. 1947, is amended to read as follows:

"27-703. Prohibited acts enumerated. The following acts and the causing thereof within the state of Montana are hereby prohibited:

~~(a) (1)~~ The manufacture, sale or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.

~~(b) (2)~~ The adulteration or misbranding of any food,

1 drug, device, or cosmetic.

2 ~~(e)~~ (3) The receipt in commerce of any food, drug,
3 device, or cosmetic that is adulterated or misbranded, and
4 the delivery or proffered delivery thereof for pay or
5 otherwise.

6 ~~(d)~~ (4) The sale, delivery for sale, holding for sale,
7 or offering for sale of any article in violation of ~~section~~
8 27-712 or 27-717.

9 ~~(e)~~ (5) The dissemination of any false advertisement.

10 ~~(f)~~ (6) The refusal to permit entry or inspection or to
11 permit the taking of a sample, as authorized by ~~section~~
12 27-722.

13 ~~(g)~~ (7) The giving of a guaranty or undertaking which
14 guaranty or undertaking is false, except by a person who
15 relied on a guaranty or undertaking to the same ~~effect~~
16 ~~(effect)~~ signed by, and containing the name and address of
17 the person residing in the state of Montana from whom he
18 received in good faith the food, drug, device, or cosmetic.

19 ~~(h)~~ (8) The removal or disposal of a detained or
20 embargoed article in violation of ~~section~~ 27-706.

21 ~~(i)~~ (9) The alteration, mutilation, destruction,
22 obliteration, or removal of the whole or any part of the
23 labeling of, or the doing of any other act with respect to a
24 food, drug, device, or cosmetic, if such act is done while
25 such article is held for sale and results in such article

1 being adulterated or misbranded.

2 ~~(j)~~ (10) Forging, counterfeiting, simulating, or falsely
3 representing, or, without proper authority, using any mark,
4 stamp, tag, label, or other identification device authorized
5 or required by regulations promulgated under the provisions
6 of this act or of the ~~Federal Act~~ federal act.

7 ~~(k)~~ (11) The using, on the labeling of any drug or in
8 any advertisement relating to such drug, of any
9 representation or suggestion that an application with
10 respect to such drug is effective under ~~section~~ 27-717, or
11 that such drug complies with the provisions of such section.

12 ~~(l)~~ (12) In the case of a prescription drug distributed
13 or offered for sale in this state, the failure of the
14 manufacturer, packer, or distributor thereof to maintain for
15 transmittal, or to transmit, to any practitioner licensed by
16 applicable law to administer such drug who makes written
17 request for information as to such drug, true and correct
18 copies of all printed matter which is required to be
19 included in any package in which that drug is distributed or
20 sold, or such other printed matter as is approved under the
21 ~~Federal Act~~ federal act. Nothing in this paragraph shall be
22 construed to exempt any person from any labeling requirement
23 imposed by or under other provisions of this act.

24 ~~(m)~~ (13) (Counterfeiting trade-marks).

25 ~~(n)~~ (a) Placing or causing to be placed upon any drug

1 or device or container thereof, with intent to defraud, the
2 trade name or other identifying mark, or imprint of another
3 or any likeness of any of the foregoing; or

4 ~~(2)~~ (b) Selling, dispensing, disposing of, or causing
5 to be sold, dispensed, or disposed of or concealing or
6 keeping in possession, control, or custody, with intent to
7 sell, dispense, or dispose of, any drug, device, or any
8 container thereof, with knowledge that the trade name or
9 other identifying mark or imprint of another or any likeness
10 of any of the foregoing has been placed thereon in a manner
11 prohibited by subsection ~~(1)~~ (a) hereof; or

12 ~~(3)~~ (c) Making, selling, disposing of, or causing to be
13 made, sold, or disposed of or keeping in possession,
14 control, or custody, or concealing, with intent to defraud,
15 any punch, die, plate, or other thing designed to print,
16 imprint, or reproduce that trade name or other identifying
17 mark or imprint of another or any likeness of any of the
18 foregoing upon any drug, device, or container thereof.

19 ~~(a) Dispensing or causing to be dispensed a different~~
20 ~~drug or brand of drug in place of the drug or brand of drug~~
21 ~~ordered or prescribed without the express permission in each~~
22 ~~case of the person ordering or prescribing.~~

23 ~~(e)~~ (14) The using by any person to his own advantage,
24 or revealing, other than to the state board, or officers or
25 employees of the department, or to the courts when relevant

1 in any judicial proceeding under this act, any information
2 acquired under authority of this act concerning any method
3 or process which as a trade secret is entitled to
4 protection.

5 ~~(15)~~ The distribution in commerce of a consumer
6 commodity, as defined in this act, if such commodity is
7 contained in a package, or if there is affixed to that
8 commodity a label, which does not conform to the provisions
9 of this act and of regulations promulgated under authority
10 of this act, ~~provided, however, that this~~ This prohibition
11 ~~shall~~ does not apply to persons engaged in business as
12 wholesale or retail distributors of consumer commodities
13 except to the extent that such persons;

14 ~~(1)~~ (a) are engaged in the packaging or labeling of
15 such commodities; or

16 ~~(2)~~ (b) prescribe or specify by any means the manner in
17 which such commodities are packaged or labeled.

18 ~~(16)~~ The labeling or packaging of a food, drug, or
19 cosmetic which fails to conform with the requirements of
20 this act.

21 ~~(17)~~ It is unlawful for any person to sell or offer
22 for sale any product which is in semblance of honey and
23 which is labeled, advertised, or otherwise represented to be
24 honey, if it is not honey. Any product sold in semblance of
25 honey which is a blend or mixture of honey and other

1 ingredients must be labeled in such a way that the name of
 2 the main ingredient added to the honey will be printed so
 3 that it will be as prominent and conspicuous as the word
 4 honey. The word "imitation" ~~shall~~ may not be used in the
 5 name of a product which is in semblance of honey whether or
 6 not it contains any honey. The label for a product which is
 7 not in semblance of honey and which contains honey may
 8 include the word "honey" in the name of the product, and the
 9 relative position of the word "honey" in the product name,
 10 and in the list of ingredients, when required, shall be
 11 determined by its prominence as an ingredient in the
 12 product."

13 Section 11. Section 66-1523, R.C.M. 1947, is amended
 14 to read as follows:

15 "66-1523. Wrongful labeling. (1) It ~~shall be~~ is
 16 unlawful for any person who prepares prescriptions, drugs,
 17 medicines, chemicals, or poisons ~~willfully, to purposefully~~
 18 or negligently, or ignorantly to omit to label the package
 19 or receptacle, or label it falsely, substitute an article
 20 different from the one ordered or deviate in any manner from
 21 the requirements of an order or prescription.

22 (2) No person may substitute a drug different from the
 23 one ordered or deviate in any manner from the requirements
 24 of an order or prescription, except as provided in the
 25 Montana Drug Product Selection Act.

1 ~~(2)~~ (3) On prescription drugs, the label shall contain
 2 the name and strength of the drug, unless the prescriber
 3 otherwise specifies, except as provided in the Montana Drug
 4 Product Selection Act."

5 Section 12. Penalties. (1) In addition to all other
 6 penalties provided by law, a person who violates the
 7 provisions of [sections 3, 4, or 5] or any rule promulgated
 8 as provided in [section 9] shall be fined no more than \$250
 9 for each violation.

10 (2) The penalty imposed under this act may be remitted
 11 or mitigated upon such terms and conditions as the board of
 12 pharmacists considers proper and consistent with the public
 13 health and safety.

14 (3) A civil penalty imposed under this act becomes due
 15 and payable when the person incurring the penalty receives a
 16 notice in writing from the board of pharmacists. The notice
 17 shall be sent by registered or certified mail and must
 18 include:

19 (a) reference to the particular sections of the
 20 statute or rule;

21 (b) a short and plain statement of the matters
 22 asserted as charged;

23 (c) a statement of the amount of the penalty or
 24 penalties imposed; and

25 (d) a statement of the person's right to request a

1 hearing.

2 (4) The person to whom the notice is addressed has 20
3 days from the date of the notice in which to make written
4 application for a hearing before the board of pharmacists.

5 Section 13. Severability. If a part of this act is
6 invalid, all valid parts that are severable from the invalid
7 part remain in effect. If a part of this act is invalid in
8 one or more of its applications, the part remains in effect
9 in all valid applications that are severable from the
10 invalid applications.

-End-

PUBLIC HEALTH WELFARE & SAFETY COMMITTEE

45th Legislature

Bill No.	Subject Matter	Date In	Sponsor	Hearing Date	Committee Action	Date Out
HB 286	MONTANA DRUG PRODUCT SELECTION ACT.	1/20/77	Palmer, Hansen, et al	HEARD BY PROBLEMS OF THE ELDERLY SUBCOMM.	DO PASS AS AMENDED	2/22/77
HB 300	TO GENERALLY REVISE THE LAWS RELATING TO LICENSURE OF RADIOLOGIC TECHNOLOGISTS.	1/20/77	J. Gunderson	2/3/77	DO NOT PASS AS AMENDED DO PASS AS AMENDED	2/17/77 2/23/77
HB 301	TO REQUIRE THAT A VETERINARIAN ACTIVELY ENGAGED IN THE PRODUCTION OF LIVESTOCK OR OTHER AG. COMMODITIES BE PLACED ON BOARD OF HEALTH.	1/20/77	Ellerd, Davis, et al	2/22/77	DO PASS AS AMENDED	2/22/77
HB 303	TO REQUIRE THE BD. OF MED. EXAMINERS TO ISSUE A LIMITED LICENSE TO A PHYSICIAN CURRENTLY EMPLOYED BY A STATE INSTITUTION.	1/20/77	Menahan	2/10/77	DO NOT PASS	2/22/77
HB 307	TO REMOVE THE STATUTORY QUALIFICATIONS FOR THE DIR. OF HEALTH & ENVIRONMENTAL SCIENCES.	1/20/77	Menahan	2/3/77	DO PASS AS AMENDED	2/17/77
HB 330	TO ESTABLISH A PROGRAM OF SUBSIDIES FOR THE ADOPTION OF HARD-TO-PLACE CHILDREN.	1/21/77	Kessler, Bardanouve, et al	2/1/77	DO PASS	2/1/77

February 22, 1977

PUBLIC HEALTH, WELFARE AND SAFETY COMMITTEE PROCEEDINGS:

A meeting of the House Public Health, Welfare and Safety Committee was held on Tuesday, February 22, 1977 at 10:00 a.m. in Room 431 of the State Capitol. All members were present except Reps. Menahan, Palmer, Colburn, Gould and Kimble, who were excused.

In the absence of the Chairman, Vice-chairman Holmes called the meeting to order. After some discussion, the committee voted to begin bill hearings immediately.

The first bill to be heard was HOUSE BILL 301. Rep. Ellerd as chief sponsor explained the bill and the reasons behind it. He presented several amendments. He also submitted a letter from the Montana Veterinary Medical Association, stating their support of the measure. Dr. J. W. Glosser, Department of Livestock, then spoke. There are nine major parameters in the human health sector that the veterinarian plays an active role in. Mons Teigen, Montana Stockgrowers, Woolgrowers and Cattlemens Association, spoke next. The livestock industry would feel much more comfortable if the Board of Health had a veterinarian on it, as well as a doctor. Jess Kilgore, a rancher and member of the Agriculture Protective Association, which represents the people of Gallatin County, spoke in support of the bill. Rod Gudgel, Pharmaceutical Association and the Nursing Home Association, felt that the Board should include a pharmacist and a nursing home administrator as well.

There were no opponents to HOUSE BILL 301. The sponsor closed. Questions were asked. The sponsor stated that he was not in support of Mr. Gudgel's proposed amendments.

HOUSE BILL 805 and HOUSE JOINT RESOLUTION 73 were then heard. These two pieces of legislation were the alternative committee bill and resolution which were drafted in lieu of the bill introduced by Rep. Eudaily.

HOUSE BILL 805 inserts "offensive violence" into the present criminal statute dealing with offensive sexual material in film previews which are viewed by minors. This definition is patented after the definition of offensive sexual material. William L. Romine, Theater Owners Association then spoke; see prepared statement. He expressed his association's neutrality towards the bill, in view of the fact that they had not yet been able to study it in detail. Tom Keegan, Motion Picture Association of America, spoke next, expressing their support of the bill.

There were no opponents to HOUSE BILL 805. There were no questions.

February 22, 1977

HOUSE BILL 724 - Rep. Colburn moved that it DO PASS. Motion carried with Reps. Stobie, Vinger and Wyrick voting no and Rep. Metcalf abstaining.

The bills heard by the Problems of the Elderly Subcommittee were then presented, with recommendations made by that subcommittee. Rep. Palmer presented the subcommittee reports and explained the subcommittee's actions on the following bills, one by one.

HOUSE BILL 52 - This bill received unanimous subcommittee approval of the motion DO PASS AS AMENDED. The recommendation was then accepted by the committee.

HOUSE BILL 61 - The subcommittee offered several amendments and it was moved that AS SO AMENDED HB 61 DO PASS. Recommendation accepted.

HOUSE BILL 255 - The sponsor had requested that this bill be tabled. Rep. Colburn moved that the bill be TABLED. Motion carried unanimously.

HOUSE BILL 286 - Amendments were submitted, see copy. This bill had received a DO PASS AS AMENDED recommendation by a subcommittee, vote of 4 to 1. Rep. Porter then made a minority report, having been the one dissenting vote. (1) The patient can either contact the doctor directly or through the pharmacist and receive lower priced drugs; this is presently allowed in all 50 states. (2) This bill is aimed only at senior citizens. (3) Testimony was given by at least two senior citizens who said that they did not want their prescriptions altered without express permission from their doctors. (4) Savings would be minimal and might in the long run raise the price of all drugs. (5) Section 8, paragraph (2) states that if there were any adverse effects from a substitute drug, the patient would have no recourse. (6) Research could be cut off if this bill were passed. Rep. Colburn then made a motion, in view of Rep. Porter's statements, that HB 286 DO NOT PASS. Rep. Palmer then spoke on the motion. This bill essentially brings the pharmacist into the picture of total health care that is being provided for the customer. Only one section of the law is being changed. At present, pharmacists do not want to bother with calling doctors in order to obtain permission to use generic equivalents. If there is a question in the doctor's mind, he can stipulate on the prescription that no substitution be made. The customer can request that the drug not be substituted, also. If there is any doubt on the pharmacist's part, he would simply not substitute. There has not been one recorded death due to generic drug-related accidents. Discussion then took place. This bill would not force the pharmacist

to use generic equivalents. Rep. Cooney stated that if the majority of the senior citizens feel that they can get a savings on this, then the Legislature should opt to give them this opportunity. Rep. Palmer pointed out that much more money was spent on advertising than on research. Rep. Ryan then expressed his opinion that this bill should never have been referred to the subcommittee, and that this was only a smokescreen to get supporters. "This business of savings is certainly not in the bill. A pharmacist can substitute anything that he wants. This is a bad bill and addresses nothing." Rep. Palmer expressed resentment of Rep. Ryan's accusations. He also pointed out that 21 states have adopted similar legislation. The Montana Medical Association has taken no position on the bill. The Pharmaceutical Association is in support of the ability to substitute generic drugs by the pharmacists. Question was then called for and the motion of DO NOT PASS AS AMENDED failed. Rep. Palmer then made a motion that the bill DO PASS AS AMENDED. The votes were switched at the consent of the committee members.

HOUSE BILL 350 was then considered. This bill received a 4 to 1 recommendation of DO PASS. Rep. Gould had been opposed. Rep. Porter quoted from a comment made by Rep. Kimble that "This bill will not get through this time, but it has to be started and this is an effort to get the aged into a place where they can be properly viewed and cared for." Rep. Gould then spoke. (1) He is opposed to the cost factor; this is money that will be lost from services. (2) Visual services. If this function is put into Aging, a big majority of the persons involved will not be senior citizens. (3) Medicaid. There is a bigger share of welfare recipients who are not senior citizens involved in this area, also. Rep. Harper expressed agreement with Rep. Gould's points. He said that this was not the time nor the place for the bill, and it should be disposed of in committee. Rep. Kenny expressed support of the bill, and said that whether or not the bill was killed, the Legislature should begin considering the senior citizen. Rep. Colburn moved that the bill DO PASS AS AMENDED; the vote was tied. The following day Rep. Gunderson submitted her vote which was in favor of the bill and as a result the committee reported DO PASS AS AMENDED.

HOUSE BILL 360 - The subcommittee recommended that it DO PASS, unanimously. Rep. Fedra moved that the subcommittee report be adopted; motion carried unanimously.

HOUSE BILL 569 - This bill will have to go to the Appropriations committee. The subcommittee unanimously recommended that it DO PASS AS AMENDED. Rep. Colburn moved adoption of

COMMITTEE ON PUBLIC HEALTH, WELFARE AND SAFETY

HOUSE BILL NO.	ENTERED COMM. 1977	DATE CONSIDERED 1977	OUT OF COMM. 1977	DO NOT DATE 1977	DO NOT PASS DATE 1977	DO PASS AS AMEND. DATE 1977	BE CON- CURRED IN DATE 1977	BE CONC. IN AS AMENDED DATE 1977	BE NOT CON- CURRED IN DATE 1977
30	Feb. 2	Feb. 24	Feb. 24				Feb. 24		
173	Jan. 29	Mar. 3	Mar. 3				Mar. 3		
174	(Mar. 9 (Feb. 11	Mar. 3	Mar. 10 Mar. 5	(Be Concurred In-3/5)			(Mar. 10--WITHOUT RECOMMENDATION) AMENDED		
176	Feb. 2	Mar. 5	Mar. 8				Mar. 8		
184	Feb. 17	Mar. 8	Mar. 8				Mar. 8		
219	Feb. 8 Mar. 10	Mar. 8	Mar. 8				Mar. 8 (AMENDED) Mar. 15		
227	Feb. 8	Mar. 10	Mar. 15				Mar. 15		
236	Feb. 8	Mar. 10	Mar. 17				Mar. 17 (AMENDED)		
286	Mar. 2	Mar. 29	Mar. 31				Mar. 31--WITHOUT RECOMMENDATION AMENDED		
294 298	April 6 Feb. 16	Mar. 10	Apr. 6 Mar. 28	(to Local Govt.)			Mar. 28--WITHOUT RECOMMENDATION AMENDED		
300	Mar. 5	Mar. 19	Mar. 19				Mar. 19		
307	Mar. 2	Mar. 22	Mar. 22				Mar. 22		
318	Feb. 17	Mar. 22	Mar. 22				Mar. 28		
330 338	Feb. 10 Mar. 21	Mar. 12 Mar. 26	Mar. 17 Mar. 28				Mar. 17 (AMENDED) Mar. 28		
360	Mar. 2	Mar. 19	Mar. 25				Mar. 25 (AMENDED)		
408	Feb. 17	Mar. 17	Mar. 17				Mar. 17		

e Separate Sheet for Senate, House Bills, and Resolutions)

MINUTES OF THE MEETING

PUBLIC HEALTH, WELFARE AND SAFETY COMMITTEE

March 29, 1977

The thirty-fourth meeting of the Senate Public Health, Welfare and Safety Committee was called to order in Room 405 of the State Capitol Building by Chairman Stan Stephens on Tuesday, March 28, at approximately 11:00 A.M.

ROLL CALL: All members of the Committee were present.

CONSIDERATION OF HOUSE BILL 455: Chairman Stephens turned the meeting over to Representative Meloy, who introduced his bill as one which would correct a deficiency which arose when the Uniform Probate Code was passed. The bill will make a technical change in that, now, the Attorney General does not receive notice of alien heirs in escheated estates - if bill passed, notice would be demanded of the personal representatives or special administrators. Said notice would be given the Attorney General within 30 days of completing and filing the inventory and statement of value. The notice would include the names and addresses of the alien heirs, devisees, legatees, or beneficiaries in the estate; the share or proportionate share of each of the alien heirs; the stated value of the entire estate.

The only witness at this hearing was Mike McGraff, representing the Justice Department, who said the bill has a very limited application and it only applies in the statute that is referred to on line 14, 91A-2-111 that states that no person is disqualified on the basis of being an alien heir unless that country is a country in which the United States does not have an existing reciprocity agreement with (that applies to approximately 4 to 5 countries). That's the only application that this bill has. Escheated estates is where someone dies without heirs that estate reverts to the State of Montana by virtue of escheate.

There were two questions: (1) how did this bill get into Public Health! and (2) why is the effective date of this bill upon passage rather than the usual date for bills (just in case there would be any escheated estates between now and July 1st).

CONSIDERATION OF HOUSE BILL 286: With the hearing room filled to capacity, Chairman Stephens opened the hearing on this bill and turned the meeting over to Representative Palmer. The Representative's opening testimony on his bill was lengthy - the bill, known by its short title as "The Montana Drug Product Selection Act" would allow the pharmacists to substitute a chemically identical drug product in the place of a more expensive name brand item. (See Exhibits "A", "B", and "C".)

March 29, 1977

Witnesses were as follows:

Rod Gudgel, Montana State Pharmaceutical Association
Jim Murray, Montana State AFL-CIO
Evelyn Johnson, Missoula Sr. Citizens Center
Oliver Dahl, Executive Director, Montana Senior Citizens Assn.
Mrs. W. L. Thompson, Senior Center
Steve Gunderson, representing Montana Farmers' Union
Representative Porter, Billings
Norman Howell
Ed Doig, registered pharmacist, Livingston
L. T. Loendorf, Montana Medical Association
Brad Stoick, pharmacy and Stoick Drug
Gerald Neely, Montana Medical Association
Dr. Agnew, Billings

Rod Gudgel, testified first, saying his Association conducted a mail ballot on the question of repeal of the Anti-Substitution laws prior to the session, with the outcome being 105 to 45 in favor. Sections 10 and 11 of this bill deal with repeal of the anti-substitution laws and of course, our support in terms of the Association's position. However, some other sections I would like to point out to you are inappropriate: on page 3, lines 10 and 11; House amendment that the pharmacist, when selecting a drug for substitution make a determination that the drug is therapeutically bioequivalent and bioavailable. This is a decision that there are virtually no practicing pharmacists who are in a position to make. The effect of this, then, is that there would be no substitutions (but even a physician would find it impossible to make this decision). The information required for such decision-making is simply not available. For this reason, Gudgel made an amendment to the sections where "therapeutically" appears in the bill (see proposed amendments on Montana State Pharmaceutical Association hand-out, Exhibit "D").

Mr. Gudgel drew the penalty provisions in the bill to the Committee's attention (page 12, Section 12) and said that the possibility exists here that there would be actual fines imposed by the Board of Pharmacists on the finding of a violation. This is a departure from the usual kind of penalty provision except, perhaps in OSHA, and some of these now are being contested in courts. Also, where should the fine money collected go - to the general fund or to a special ear-marked revenue account of the Board of Pharmacy, or where? If the bill is acted upon, some action is needed in this area.

Jim Murray testified that his organization went on record last August in unanimous support of Resolution 59:

"Be it resolved that the state AFL-CIO strongly supports and encourages allowing the pharmacists, because of their schooling, 5 years, to have the flexibility to dispense, if one exists, a less expensive but chemically identical drug, as opposed to an expensive name brand."

The members of the organization recognize that the drug industry is dominated by a hand-full of giant firms. We feel

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the situation is not in the best interests of the consuming public because of the adverse effect this corporate control has on drug pricing. The elderly has a large burden in drug costs. Therefore, they feel HB286 is a step in the right direction in providing needed competition in drug pricing.

Evelyn Johnson testified that this bill does not require the pharmacist to substitute, it only provides they can. HB286 would provide a much needed savings for senior citizens and other low income persons. Mrs. Johnson also read a letter from Walter D. Taylor, Executive Director of Missoula Senior Citizens Center (see Exhibits "E" and "F").

Oliver Dahl testified next in support of the bill, saying senior citizens support passage of HB286 because of the spiraling costs of medical care which severely affects the elderly person's ability to pay for life's necessities. Forty-one percent of Montana's elderly are below the poverty qualifications guidelines.. (See Exhibit "G".)

Mrs. Willard Thompson read a statement concerning an elderly couple who cannot buy food because of high medicine costs (See Exhibit "H").

Steve Gunderson read from his group's policy and program which was adopted at their State convention last Fall:

"The Montana State Farmers Union strongly endorses the changing of the current anti-substitution law to allow the pharmacists to substitute a chemically equivalent drug."

End of proponents.

Representative Howard Porter, one of two main opponents, testified as an "oldster" and also as one who is on the House Subcommittee on Aging. The Representative said that the bill duplicates what we can do right now. All the oldster has to do is say to the pharmacist, "Please, would you call my doctor and see if there is a drug that will do the same thing for me but cheaper?" - this happens all the time. We are going to a great deal of trouble to legislate something that exists. It is so easy.

The National Council of Aging hired the Harris Poll for some research: findings - 51% of the general public think people over 65 are in poor health but only 21% of the people over 65 think they are in poor health. We are getting overly dramatic as far as the need is concerned - 44% of the general public think that people 65 and over do not have adequate medical attention but those over 65, only 10% think they have inadequate attention.

Pricing - the price of drugs will come down by this bill passing? It didn't come down in Michigan, nor in Saskatchewan. In the Canadian province, it actually went up because of the rising insurance rates.

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Mr. Porter called the Committee's attention to page 6, Subsection 2, line 8 where it refers to the doctor's obligation, or lack of it, once the pharmacist substitutes, and added the comment of someone in the House when this bill was there ('this is the attorneys' Relief Act'). Based upon the price of the drugs in Michigan experience, and any other state that has a similar law, the price does not come down and likelihood price will go up. In 1967-75, pharmaceuticals went up 9.4%, while other things went up 75%. Only 7% of the health care dollars is spent on prescription medicine, against 12% in 1960. Here's one place where private enterprise has done a tremendous job, they have held the line on inflation. If something of this kind is done (passage of bill), who is going to do the research and investigation, who is going to create the market for new drugs that is going to keep people alive longer? Are we going to get penny-pinching when it comes to our health? The doctor knows you and he will take into consideration your physical make-up and then make his decision regarding your medicine.

Bioequivalent, etc., is complicated. Formularic tables etc. are created in hospitals where you have doctors, pharmacists that go through this meticulously - not on the whim of saving a few cents here or there. This work is precisely done.

Pharmaceutical houses don't make lots of money. Years ago, Mr. Porter said, he invested in their stock, and never made any money. They plow their money back into research to keep us alive. All the patient has to do is say, "Please call my doctor and see if there's anything less expensive".

Norman Howell testified briefly concerning his beliefs about doctors and drugs, saying the doctor knows you and what your body will tolerate, plus the fact he thinks not all drugs are manufactured the same. His doctor says, "I have had very good luck with this medicine" meaning he knows that brand and would not hesitate to prescribe it.

Ed Doig was the other main witness for the opposing side. He introduced himself as a member of: Park County Pharmaceutical Association, Board of Directors of the Montana State Pharmaceutical Association, American Pharmacists Association, Medicaid-Medicare Advisory Council of the State.

Doig brought several letters from other pharmacists around the State with him, to be submitted to record (see Exhibits

His position on the bill was "complete opposition". Doig said many pharmacists in Montana may be in favor of drug substitution to some degree but he has not talked to one single pharmacist who is in favor of this bill. (see complete testimony in Exhibit "I".) He was very uncomplimentary to Mr. Gudgel

L. T. Loendorf testified in a rather neutral manner and signed the testifying sheet as "oppose unless amended". He said the most important thing is that the patient gets a drug that

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helps him. If you substitute a cheaper drug and that drug does not help him, he has to go back again and buy another drug. The MMA took no position on the bill in the House, but did offer some amendments, and those amendments were that the drug, as well as being therapeutically equivalent, be "bioequivalent". Incidentally, the language adopted the pharmacists offered and MMA supported. Today, Loendorf said, he is surprised the proposed amendments by pharmacists would remove that same language which is the only thing that assures the patient get an equivalent drug, and then substitute "generically equivalent" which is not defined anywhere in the bill.

Substitution involves some risk - so if its made, there should be a corresponding benefit to the people who receive that substituted drug. Unless this bill insures that and there are some savings going to be passed on, it seems to Loendorf it is not worthy of passage.

The MMA would propose some changes if the Committee passes this bill which would insure the above. The patient, also, should be notified of the amount of the savings, as well as the fact that he does not have to accept the substitute. (Exhibit "K".)

Page 3, Section 3, Line 6 pointed out to Committee for comment.

Page 4, line 19: Why should a substitution be made for an "equally" priced drug? There is no benefit. Strike.

Typed amendments regarding prescription forms to be added to bill and also to amend page 4, line 4: patient should be notified of the savings (that was deleted out in the House).

Page 4, line 21-25: the pharmacist must pass on the full amount of the savings to the patient - Loendorf said this is one of the main parts of the bill and must be put back in.

Page 5, Section 6 regarding pharmacist keeping a record of drug substitutions. Their amendment addresses this. This is important because if a patient has an adverse reaction, the doctor should know what the pharmacist substituted.

Because of the time factor, Chairman Stephens cut the testimony.

Brad Stoick identified himself to the Committee, then submitted to record his written testimony (see Exhibit "J") and also submitted letters from pharacists around Missoula area.

Gerald Neely said that, in regard to the amendments proposed by the Montana State Pharmaceutical Association today, in substituting the "generically equivalent" words, if that amendment were adopted, it would merely mean that substitution could be allowed for those drugs which were chemically or established name-wise the same. Thereby, it would allow drug products to be substituted that were not generally equivalent, that were not bioequivalent, and would also allow substitution of drugs that were not therapeutically equivalent. If substitution

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is authorized, it is very critical that the same drug, with the same therapeutic effects on the disease, the same chemical equivalency, and also the same rate of absorption.

So, if the Montana State Pharmaceutical Association amendments are adopted, it will only mean that they have the same brand name or the same chemical name and not in any way, shape or form the total equivalency of those drugs.

Totally out of time for testimony, all other testimony in written form was given to Committee Secretary Allen to submit to record.

Closing remarks by Representative Palmer covered some of the preceding opposing testimony, in that he thought it was a "smoke screen". Mr. Palmer made the point, the general public does not know that equivalent drugs exist. Why don't they know - because, as he said, of the ability the big manufacturers have of convincing us that the brand names are the best. Mr. Palmer gave some examples of price differences between generic and brand-named drugs. He said we should provide this mechanism for savings to consumer. The issue is: Do you believe the pharmacists in this state have the ability to be able to substitute a chemically identical drug that is going to be a potential for savings? The pharmacists have the ability, said Representative Palmer, because he talked with the Dean of the School of Pharmacists, as well as several professors who attest to the school giving the pharmacists that ability.

Questions:

1) Senator Roberts asked what would happen if we simply deleted that part of our law that is the anti-substitution portion - Representative Palmer said it would give a free hand to the pharmacists to substitute or not. The sections beyond the substitution part is consumer-oriented, for the protection of the consumer and to educate the public. What needs to be done, Palmer said, is repeal the substitution section but to provide safeguards for the consumers.

2) When Senator Roberts asked Mr. Doig if he would support that approach, the answer was absolutely negative and he added that the pharmacists are already required by the State Board of Pharmacy to have a sign saying a generic drug is available and all they have to do is contact their physician.

(To which Representative Palmer responded that he petitioned the Board last year to do this as a part of educating the public. However, some pharmacists were known to say in some instances, "we don't want to bother the doctor". So, there is no opportunity to provide the consumer with that savings.

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The pharmacist should be a part of the health service field. He has the knowledge. It is a working together.)

3) When Senator Stephens questioned Mr. Gudgel about the term, "generically equivalent" and its definition, Mr. Gudgel referred to the testimony of Mr. Neely and added that he checked this phrase out with the American Pharmaceutical Association first and it was confirmed - he also called the School of Pharmacy (Missoula) for confirmation, that it covered the kind of substitution required. The only reason for a modification is that it simply is impossible to meet the terminology that is there at the present time.

4) Senator Olson asked Representative Palmer if he knew of any other states that introduced this legislation in the past year - Rep. Palmer said Colorado did, and it passed. It was mentioned, also, that some 20 states currently have a similar law. However, Rep. Porter said our neighboring states voted down similar bills.

5) Senator Norman questioned Rod Gudgel concerning the amendments he proposed by asking exactly what amendments would do - Gudgel said it would make it possible for a pharmacist to use his professional judgment and make a substitution.

The Senator asked if it would make any difference whether it were bioequivalent or bioavailable - Gudgel said, no, just so it were generically equivalent. To which the Senator commented that that would just about take care of the bill - Mr. Gudgel said it would then make it workable for the pharmacist and the Senator responded, "but what about the patient?"

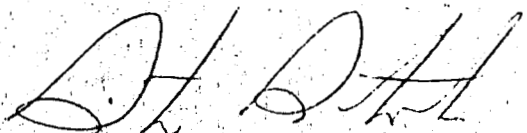
Other questions established that the sponsor is not terribly concerned that the bill's section on pharmacists passing savings on to consumers has been stricken because he feels they would morally and ethically do this anyway. If not, he stated the problem could be addressed next session.

Also, the prescriber places a high priority on pharmacists' calls to him (doctor) and a substitution question by phone usually is answered quickly (no delay or put-off, as earlier suggested). Dr. Agnew from Billings testified to this.

If the pharmacists do not now have the ability to substitute, the sponsor said, we better look into the pharmacy schools.

There are about 100 large companies: the greatest percentage any one company has in the market, is 7%.

That concluded the hearing on this bill, with NO ACTION BEING TAKEN AT THIS TIME on HB286.



STAN STEPHENS, Chairman

MARCH 29, 1977

ROLL CALL

PUBLIC HEALTH, WELFARE AND SAFETY COMMITTEE

45th LEGISLATIVE SESSION - 1977

DATE: 3/29/77

[illegible]

March 29, 1971

TESTIFYING

NAME:

REPRESENTING:

ON BILL #

SUPPORT,
OPPOSE OR
AMEND?

(Please leave any prepared statement with Secretary)

BRAD STOICK	PHARMACY & STOICK DRUG	HB 286	OPPOSE
Ed Doig, Reg Pharmacist	Livingston Drug	HB 286	OPPOSE
Byron E Dodd RPh.	Smith Drug	HB 286	OPPOSE
Jim Murray	Mont. State AFL-CIO	HB 286	Support
Del Steiner	Gibson Pharmacy & Sel-T	HB 286	OPPOSE
Red Gudgeon	MSPA	HB 286	Support & Amend
James H. Neuman	Missoula	HB 286	OPPOSE
MIKE McGRATH	ATTY GENL	HB 455	SUPPORT
Miss Wil Anderson	Senior Center	HB 286	Support
Robert Johnson	Missoula Sr. Ctr	HB 286	Support
Loendorf	MMA	286	Oppose unless amended
Oleum M. Dahl	USFSG	286	Support
Mr Agnew	Billings		
Gerald Neely	MMA		Oppose w/ Amend.
Steve Gunderson	MFU (Monting Farmers Union)	286	Support
Rep. Porter			

DATE MARCH 29, 1977

COMMITTEE ON PUBLIC HEALTH, WELFARE AND SAFETY

Houses
BILL NO. 286

VISITOR'S REGISTER

NAME	REPRESENTING	Check One	
		Support	Oppose
Mary Ann Ritchey	Cornwallis High School		
Brian Sutton	Cornwallis High School		
Kyle Craig	Lewington Mt.		✓
Todd Koepf	Observing		
Denis Gort	ST. Peter's Hospital Helena, Mt.		✓
Ed McGee	None		✓
Neil Porter	None		✓
Del Steiner	Gibson Pharmacy		✓
Russ Morgey	Registered Pharmacist #1818		✓
Rod Gudgeon	MSPA	—	—
Loendorf	MMA		
Quentin Deas	711A Pa	✓	
Walter Hammond	self	✓	
Mary E. Ryan	Senior Citizens Mission	✓	
G. Brian Zins	Ut. Medical Assoc.		✓
Edward Agnew MD	Mont. Med. Assoc.		✓
Dr. Brown			✓
Henry L. Walton	Montana State Pharmaceutical Assoc.	✓	
John T. Zander	Ut. Med. Assoc.		✓
Gerard Neely	Mont. Med. Assoc.		✓

EXHIBIT "A"

March 29, 1977

Mr. Chairman:

My name is Bob Palmer, and I am the chief sponsor of House Bill 286, to be known as "The MONTANA Drug Product Substitution Act". House Bill 286 will allow for pharmacists to substitute a chemically-identical drug product in place of a more expensive name-brand item.

Currently, expenditures for prescription medication by the elderly is often their greatest cost of health care. More than one out of every four persons over the age of 65 is in the government classification of poverty. Far too often, illness itself is the cause of poverty for an older American. High prices for prescription drugs are part of the problem.

For those who don't know, antisubstitution began because after World War II., the success of the U. S. drug industry had spawned a proliferation of duplicate prescription drug products made by different manufacturers, but embodying the same drug entity. However, the high prices at which drugs were being sold produced a rash of counterfeit prescription drug products on the U. S. market. The drug industry fought the counterfeiting problem, in part, by mounting its successful campaign to bring the antisubstitution laws into being. Pharmacists supported the campaign.

Times have changed, and proper regulations and safeguards have been established. The present antisubstitution laws create an environment which places undue emphasis on the trade names assigned to drug products; this, in turn, has a substantial anticompetitive effect in the drug marketing and dispensing area. Through the use of easily-remembered and catchy trade names, combined with heavy promotional activities to a relatively small population of physicians,

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E X H I B I T "B"

DRUG SUBSTITUTION

Introduction: Older Americans have been forced to pay unreasonably high prices for prescription drugs because of the anti-competitive nature of the pharmaceutical drug industry which has been created and maintained under certain state laws and regulations.

Reform legislation must be passed to eliminate this anti-competitive nature of the pharmaceutical industry and thereby enable the older Americans to buy prescription drugs at a reasonable price.

Older Americans continue to pay unreasonably high prices for prescription drugs basically because very powerful opposition to any reform legislation exists. You will see what I mean today. The Pharmaceutical Manufacturers' Association (PMA) has been most successful in protecting the interests of their membership. Through the years, PMA and Pharmacists in nearly every state enacted anti-substitution laws and laws or regulations which prohibit the posting or advertising of prescription drug prices. These measures insured consumer ignorance of Rx prices and lower-priced generic drugs. But, in state after state, these laws are now being repealed or amended by consumerist action.

The drug industry, in particular the PMA, wants to preserve its anti-competitive nature. It has been shown that the drug industry, over the past quarter century, has developed a market policy of promoting drug products exclusively to physicians.

It is estimated that brand-name manufacturers spend an average of over \$5,000 annually on every physician promoting brand names. A physician, consequently, may be compelled to prescribe

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EXHIBIT "C"

A SHORT HISTORY OF THE RISE AND FALL OF
STATE ANTISUBSTITUTION LAWS

Prepared By

NRTA-AARP Legislative Representative

Before the advent of drug manufacturing, pharmacists compounded the prescriptions written by physicians. In the absence of brand name products and antisubstitution laws, they selected the manufacturers of the ingredients they mixed into medicines, utilizing their professional expertise and judgment as to quality and economy.

Following World War II, the economic success of the drug industry in accumulating enormous profits gave rise to duplication and counterfeiting of prescription drug products. To combat the problem, the drug industry refused the obvious solution of increasing the authority of the Food and Drug Administration to regulate manufacturing and to test products. It chose instead to spend hundreds of thousands of dollars to enact state laws and regulations requiring pharmacists to dispense the manufacturer's product which the physician designated by brand name on the prescription form. Organized pharmacy set aside its professionalism for the time to help enact the antisubstitution laws restricting its own members from fulfilling their traditional responsibilities to their patients' health and economic status.

During the 1950's antisubstitution laws were quickly placed on the statute books of state after state with the justification of protecting the public health and safety. While it was the wrong

EXHIBIT "D"

MONTANA STATE PHARMACEUTICAL ASSOCIATION

House Bill No. 286

Amend as follows:

1. Amend page 3, section 3, lines 10 and 11.
Following: "opinion,"
Strike: the remainder of line 10 and 11 in its entirety.
Add: "generically equivalent."
2. Amend page 4, section 4, line 13
Following: "is"
Strike: "therapeutically"
Insert: "generically"
3. Amend page 5, section 5, line 5
Strike: "therapeutically"
Insert: "generically"

E X H I B I T "E"

My name is Evelyn Johnson. I am employed by the Missoula Senior Citizens Center and come today to speak in support of HB 286 on behalf of many of the members of our Center.

Mr. Walter Taylor, Executive Director of the Missoula Senior Citizens Center, is unable to be here today, so he sent a brief message which I will read.

HB 286 was drafted and introduced for the purpose of reducing the very high cost of prescription drugs. As you know, the bill does not require pharmacists to substitute so-called generic drugs -- it only provides that they can substitute a less expensive drug if they feel it will be as pure and effective medication as if they used the more expensive name-brand ingredients.

I feel HB 286 would provide much-needed savings to senior citizens and other low-income persons. I feel the bill deserves your support, so, on behalf of Montana's many senior citizens, I respectfully ask that this committee give HB 286 your approval.

KATHLEEN WALFORD SENIOR CITIZENS CENTER ASSOCIATION, INC.
705 South ~~424 North~~ Higgins Avenue, Missoula, Montana 59801
Phone 543-7154

March 29, 1977

Public Health Committee
Montana State Senate
Helena, Montana

In Support of HB 286

All costs in regard to health have soared to unbelievable heights in recent years, and the cost of medicine is no exception.

Senior Citizens need more medicines than the average population, so drug costs are more burdensome to them. Because seniors are limited to a fixed retirement income the high cost of drugs force many of them to live on a very low standard.

We have older couples, members of our association, who have monthly medicine bills of \$70.00.

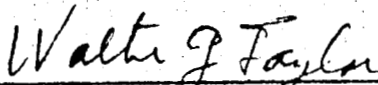
As to research costs, our patent laws protect an inventor for 17 years to recover research and development costs. Continued high prices mean unwarranted large profits.

HB 286 makes possible substantial savings on prescription drugs and, at the same time, reserves the right of choice for both the doctor and the patient.

The fact that more than twenty states have passed generic drug bills adds proof to the need for this legislation.

Passage of HB 286 will give substantial financial relief to Montana's senior citizens without adding to the tax bill.

We urge a "do pass" vote for HB 286.



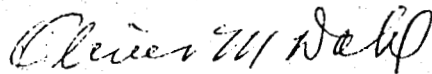
Walter G. Taylor, Executive Director

Mr. Chairman and Members of the Committee:

I am Oliver Dahl, Executive Director of the Montana Senior Citizens Association. Montana senior citizens support passage of House Bill 286. The spiraling cost of medicine and medical care severely affects the elderly persons ability to pay for these necessities. Do you realize that forty-one percent (41%) of Montana's elderly are below federal poverty guidelines? These people receive only two (2) to three (3) hundred dollars a month.

Decent medical care and decent medicine prices should be the right of every citizen --- especially those who have been relagated to live at subsistant levels through no fault of their own. And this problem will increase as the elderly population grows. If the Legislature does not pass HB 286 and other measures for seniors, the problems will just keep multiplying until they reach unmanageable proportions. I urge the Committee to pass HB 286.

Thank you,



Oliver M. Dahl

E X H I B I T "H"

My name is Mrs. Willard Thompson. I want to tell you about a case which recently came to the attention of the Information and Referral Technician in Missoula. The I and R technician is employed by the Western Montana Area Agency on Aging. When she investigated the case she found the couple, the wife of which is mentally ill, to be almost starving. The day she was there the refrigerator was ~~almost completely~~ empty except for a quart of milk and three eggs. She learned that medication for the two of them amounted to \$90 a month. This cost on top of rent and utility bills used up almost every cent of their meager income.

She was able to obtain emergency help for them, but of course it was only temporary help. Reducing their drug bill by savings which could be effected by HB 286 would provide more permanent help.

Members of the Montana State Senate:

My name is Ed Doig. I am a registered pharmacist and own Livingston Drug, an independent drugstore in Livingston. I am ~~pharmacist~~ the Park County Pharmaceutical Association, The pharmacists from Sweetgrass County, Wheatland County, Neapher County and Broward County. ~~not also, just for this~~

~~Pass out letters~~. I am also a member of the board of directors of the Montana State Pharmaceutical Association, a member of the Medicaid Medical Advisory Council for the state of Montana, the American Pharmaceutical Association and the National Association of Retail Drugists.

I am appearing before you in complete opposition to the drug substitution bill, HB 286. My presentation will be brief.

It should be made clear that many pharmacists in Montana may be in favor of drug substitution to some degree, but I have yet to talk to one single pharmacist who is in favor of this bill. Every pharmacist I have talked to is either completely opposed or is in favor of substitution with no strings attached, which is hardly possible.

As I thought this bill would be killed in the house committee, I did not appear before that group. As you know, it passed by 2 votes.

Unfortunately, I understand our pharmacy lobbyist, Mr. Rod Gudel, appeared before the house committee in favor of the controversial substitution bill - based on a survey he conducted with Montana pharmacists early last fall. This survey, I believe, is completely misleading - even to pharmacists. However, this may be due to the fact that our pharmacy lobbyist is not a pharmacist, so it is understandable if he does not fully understand the situation.

To briefly discuss our pharmacy, non-pharmacist lobbyist's survey, which I consider very misleading, (Read the statement from the questionnaire) 105 for 45 against when the question is tied in with the federal Maximum Allowable Cost/~~estimated~~ Allowable Cost regulations, which practically every pharmacist in the United States is opposed to. These regulations are not our concern here. However, this little tail on the questionnaire misled many pharmacists into voting the way they did.

Also, to illustrate how ridiculous is this questionnaire of our lobbyist is another question: 79 No 70 Yes to provide that forgoing a prescription shall be unlawful. In other words, almost half of Montana's pharmacists would like to see a law making forgoing a prescription legal!!! Isn't this ridiculous? Let's face it, one-half of Montana's pharmacists misread the question! So much for the reliability of our lobbyist, Mr. Gudel's survey which he apparently made a big deal of before the house committee.

In regard to this controversial substitution bill, HB 286, -this is a very long bill which should be compared to opening the lid on Pandora's box - especially the 2 or 3 paragraphs which are at the heart of the bill:

Read Section 5 Paragraph 2

Read Section 6 Paragraph 1 and 2

Also, this statement "consistent with reasonable judgement" - what does this qualification mean? Where does this place the responsibility if a severe drug reaction occurs, or is this some kind of a loophole or some kind of double talk? What is the concise definition of "consistent with reasonable judgement"? Should I use this, in my opinion, crap, (hold up a generic bottle) or should I use this high quality product (Peritrate bottle) in your prescription or in your family's prescription? This substitution bill states that I should use this stuff (generic bottle) from a company which does no research whatsoever, and I don't know for sure if they are even still in business. Or should I use this company's product which, on the other hand, spends millions of dollars on medical research. The product, by the way, is very widely used in the treatment of pain associated with coronary artery disease. Which would you prefer? If you or your family had coronary disease?

What will prevent an unscrupulous pharmacist from substituting a cheap product and charging a higher quality product price? Would the consumer benefit from this? Why provide an opportunity for this to happen by passing this bill.

In my drugstore, I can't for the life of me see where this bill is going to save the consumer 1¢! And I operate a very competitive store with high quality products! However, this bill would undoubtedly increase my liability insurance rates, which would immediately be passed on to the consumer in the form of higher prescription prices!

Most states don't have a drug substitution law. Many of those states that do are trying to repeal them. An example of a state that has a drug substitution law:

(Read results of Michigan's failure of substitution bill or law)

(Pass out FDA Bioavailability problem list, explain, and read Para. 1 Section 3.)

In explanation of the FDA problem list: On March 1, 1977, a list was published in "American Druggist", a highly regarded pharmacy publication. This list was just released by the FDA (Food and Drug Administration - Washington D.C.) and contains 110 drugs which have bioavailability problems and therefore could not be safely substituted without possibly endangering a patient's health. Bear in mind these are 110 basic generic drugs which may be used in combination with other drugs and are each manufactured by from 2 to 65 manufacturing companies, therefore, there could be several thousand products on the market, which require a prescription, which may have bioavailability problems and which could not be safely substituted.

The list speaks for itself as evidence that drug substitution is unwise. In fact the FDA (Food and Drug Administration, Washington D.C.) states that there may be many others which have bioavailability problems but are not listed because the FDA (the Federal government) does not have the time or money to investigate the bioavailability of every drug on the market! If the federal Food and Drug Administration does not have the time and money, how do you expect the average pharmacist to have the time, the money, facilities, or know-how to determine bioavailability of every drug on the market? (Again read Paragraph 1 Section 3 last sentence.) It doesn't make any sense whatsoever, does it?

It is my opinion that any pharmacist who substitutes would have to be out of his mind and have taken complete leave of his senses, if this bill passes or not!

In this entire substitution bill, which must be one of the longest substitution bills in the United States, Representative Palmer has failed to define a consumer! Therefore, let's define a consumer: Wouldn't you agree that consumers are you and I, your children, your families, your relatives, the rich, the poor, the young, the middle-aged, and the senior citizens??? We are all consumers!!

It makes me wonder if Rep. Palmer is simply using the consumer or consumer interest label merely to get his name on a bill. If this could be true, it is my opinion that the consumers he claims to represent would resent, very, very deeply, their being used in this manner.

I'm sure Rep. Palmer, who they say is a school teacher, (don't get me wrong, I like school teachers - I'm even married to one) but I believe that Rep Palmer is no more qualified to change the practice of medicine or the practice of pharmacy in Montana, than I would be qualified to go into Missoula and try to change the education programs in his school system!

You are all very intelligent people or you wouldn't be here in the Montana State Senate, so please - please consider this controversial bill very very carefully, with all of its unknown ramifications, - this bill which may not benefit the consumer at all or save the consumer one single penny!

The only advantage I see to this bill is that it is a vote ^{getting} mechanism and publicity for Rep. Palmer.

The dangers to the consumers and pitfalls inherent in this type of legislation, this controversial legislation, far outweighs any questionable benefits to the consumer.

Please consider the consumer first and vote a definite NO on this HB 286. You can't compromise a person's health.

Thank you for your time and consideration.

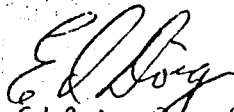

Ed Doig, Reg. Pharmacist
Livingston Drug
119 South Main
Livingston, Montana 59047

EXHIBIT "J"

SEATORS OF THE COMMITTEE

MY NAME IS BRAD STOICK, REGISTERED PHARMACIST IN MONTANA AND CO-OWNER OF STOICK DRUG IN MISSOULA.

FIRST I WOULD LIKE TO DELIVER TO THE COMMITTEE (~~WAS PRESENTED TO~~ ~~MR GUAGELS~~ ~~BY~~) OVER 20 SIGNED LETTERS FROM PHARMACISTS IN THE MISSOULA AREA WHO ARE IN OPPOSITION TO HOUSE BILL 28C.

NOW IN MY BEHALF I WOULD LIKE TO PRESENT BRIEFLY THREE POINTS FOR THE COMMITTEES CONSIDERATION REGARDING HOUSE BILL 28C.

SUBSTITUTION OF A LESS EXPENSIVE THERAPEUTICALLY EQUIVALENT DRUG FOR ANOTHER - IS PRESENTLY ACOMPLISHED BY SIMPLY CONTACTING THE PRESCRIBER AND OBTAINING THE PROPER AUTHORIZATION. - WITH THIS IN MIND IT WOULD SEEM THAT WE HAVE LEGAL SUBSTITUTION ALREADY WITHOUT LEGISLATION.

EXHIBIT "K"

AMENDMENTS TO HOUSE BILL NO. 286

Amend Section 3, page 3, by deleting lines 12 through 25, in their entirety and inserting in lieu thereof the following:

"(2) Every prescription written in this state by a prescriber shall be on prescription forms containing 2 lines for the prescriber's signature. Alongside the first line shall be clearly printed the words, 'substitution permitted'. Alongside the second line shall be clearly printed the words 'dispense as written'. The prescriber by placing his signature on the appropriate signature line has indicated his dispensing instructions to the pharmacist. Failure of the prescriber to sign either of the designated lines shall invalidate the prescription. When a prescription is communicated orally, dispensing instructions shall be given to the pharmacist. In absence of any dispensing instructions, the pharmacist shall fill the prescription as communicated to him. The pharmacist shall note the prescriber's dispensing instructions relative to substitution, on the face of the file copy of the prescription."



PROFESSIONAL VILLAGE PHARMACY



PROFESSIONAL VILLAGE 515 KENSINGTON 542-2111 MISSOULA, MONTANA 59801

3/26/77

This is to certify that I am opposed to the
Passage of HB 0286/03, as it is now written.
I would be in favor of this bill, if the legislature
would at the same time, establish & fund a state
laboratory, whose function would be to assay
every batch of generic drugs sold in the
State of Montana.

James H. Newman R.Ph.
524 Nixon Avenue
Missoula, Montana
59801

28 Mar 77

I am opposed to AB 286.

James Long MD
515 Kensington Ave
Missoula MT
59801

March 28-77

oppose AB 286

Eugene M. H.
515 Kensington Ave
Missoula, Montana

March 28, 1977

Whom it may concern:

I am opposed to HB 286 for the
wrong reason. Who will be in
charge of determining the bioavailability
so-called "generic" equivalents.
not be fooled by so-called "generic
equivalents". Until the quality of
continuing number of "lots" of
generic compound can ^{be} assayed
bioavailability.

Stephen W. Dill
501 Ford St.
Missoula, Montana
59801



Optical Center



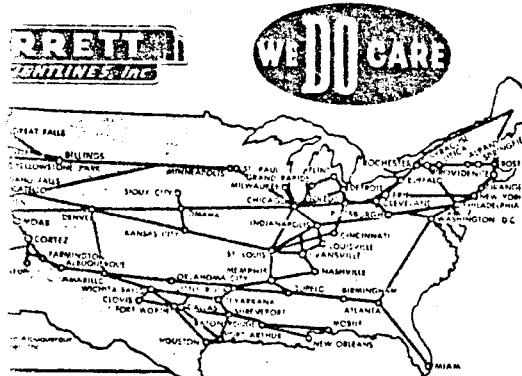
Phone 549-1484
125 E. Main
and
Professional Village
Missoula, Montana 59801

To whom it may concern:

I oppose H.B.

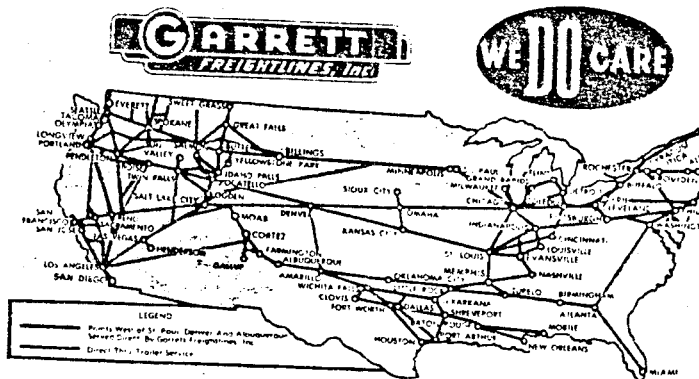
0206/03

George Kuyper
298 Whitaker St
Missoula, MT.



26 March 1977
 it may concern:
 case HB 0286/03

W. J. McKinstry M
 W. Kent.
 session of Village
 session, Mt.
 19901



28 Mar 77
 To whom it may concern
 I strongly oppose
 HB 286
 as written.

W. J. Dunlap M
 Prof. Village
 Missoula

I oppose
 HB 286

W. J. Dunlap M
 Missoula

PUBLIC DRUG CO.

JAMES T. CLAY, R.Ph.

WHITE SULPHUR SPRINGS, MONTANA 59645

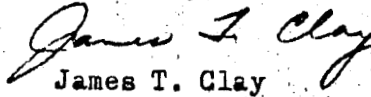
3/22/77

Mr. Ed Doig
Livingston Drug
Livingston, Mt.

Dear Ed;

I am writing to say that I support your stand against HB 286. The potential dangers to the small community pharmacies are too numerous to mention in a letter but I cannot voice my opposition to this bill in terms that are too strong.

Sincerely;


James T. Clay



FRANCISCO
Ph. 266-3325 **PHARMACY** Ph. 266-3325
GOOD HEALTH TO ALL
TOWNSEND MONTANA



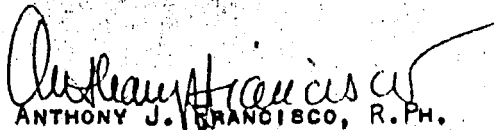
CENTRAL MONTANA'S FINEST DRUG STORE

3-22-77

TO WHOM IT MAY CONCERN:

I FIRMLY SUPPORT ED DOIG, R.PH., IN EVERY WAY REGARDING HIS
OPPOSITION TO H.B.286, THE SO-CALLED "SUBSTITUTION BILL".

IN NO WAY DO I SUBSCRIBE TO THE SUM AND SUBSTANCE OF THE BILL
AND I FEEL THAT THE CRITERION FOR THE "BALLOT" TAKEN AMONG
PHARMACISTS BY THE M.P.A. WAS MISLEADING AND TOTALLY FALSE.


ANTHONY J. FRANCISCO, R.PH.
OWNER, FRANCISCO PHARMACY
TOWNSEND, MONTANA 59644

it may concern:

As owner and operator of Corvallis Drug, I am opposed
86 on the grounds that I will have to bear the product
ility on substituted medicinals.

Yours,

Marshall Holmberg
Marshall Holmberg
Corvallis Drug

Box 161

Corvallis, Montana 59828

PHONE 549-5171

MISSOULA, MONTANA

3-26-77

Legislature of State of Montana 1977

In Refferance to House Bill No. 286

Introduced by Palmer, Hansen, Kessler, Cooney

This is to let you know that I (Don C. Ryan) do
oppose House Bill No. 286. This is a drug substitution
bill, which in turn give the people of Montana a
substandard medication program.

The pharmacies would have to stock double inventories,
name brand for those who request quality drugs and
junk for those who want cheap.

Pharmacist would open them selves as to the the
liability as to the quality of the druge that they
will be required to use.

If the legislature would institute laboratories to
check the Bioequivalent and Bioavailable equivalent
of all drugs coming into the state.

Yours truly

Don C. Ryan
Don C. Ryan



CITY DRUG

23 March 1977

101 N. MAIN LIVINGSTON, MONTANA 59047

To Whom it may concern:

We, the undersigned Pharmacists of the Livingston Pharmaceutical Association, hereby authorize Ed Doig to speak for us and to express our views relative to HB 286, the proposed "Montana Drug Product Selection Act."

R.D. Petersen
CITY DRUG
R.D. Petersen, R.Ph.

PUBLIC DRUG
Roald J. Mogen
Roald J. Mogen, R.Ph.
T. Emil Madsen
T. Emil Madsen, R.Ph.

TROWER PHARMACY
Doug Linsted
Doug Linsted

PRESCRIPTIONS — GIFTS — COSMETICS

BIG TIMBER COLE DRUG COMPANY MONTANA
PHONE 932-2816

FOR _____ DATE _____

ADDRESS _____

R

I support Ed Doig in voting against House
Bill # 286. I am against all parts of this bill
in any manner or form.

Sincerely,

Ramona B. Holderman

Ramona B. Holderman
Reg. Pharmacist

LABEL _____

REFILL _____ TIMES _____

My name is Del Steiner, I am manager of Gibson Pharmacy, here in Helena.
I represent myself as well as my employer, who also operates pharmacies in
Billings & Bozeman. No one can fault Mr. Palmer's intent in introducing
this bill. He is making the assumption that substituting generic medication
on prescriptions will save the patient money. This might be so, although
there are examples of states with substitution laws where the amount of
money saved is insignificant. But money is not the most important aspect
of prescription medications. I am not going to delve into all the problems
of bioequivalency & bioavailability. Let's us just assume that some such
problems do exist. If any of you have doubts I have a copy of a list of
115 medications that the FDA says that there are known or potential bio-
equivalent problems. That means that about 5-10% of the commonly prescribed
drugs might have such problems. If the doctor knows of the possibility of
such a problem-- as he would under the present laws, because the pharmacist
must get his permission to make any substitution-- he can correct a thera-
peutic problem if it arises. If the prescriber does not know of the sub-
stitution, he has to assume that the TYPE of drug, rather than brand of drug,
is causing the problem. He will then have to try additional drugs, all
costing additional money. In such a situation it would not be impossible
for the original substitution to actually cost the patient more money.
Every pharmacy exists ONLY because it can satisfy the demands of its cust-
omers. If a patient requests his prescription filled with a cheaper, generic
drug we try to comply-- but we always check with the prescriber FIRST. The
present pharmacy regulations require pharmacies to post a sign to inform the
patient of the possibility of saving money by having the prescription filled
with generic drugs. So as things are now; the patient is informed of the
availability of generic drugs, he can, if he wishes, request them, AND the
doctor retains some essential control. In other words, things are running
smoothly NOW. We do NOT need this bill to become law & rock the boat.

[Handwritten signature]

PO Box 4242

Helena, MT 59601

45

Mineral Pharmacy
Superior, Montana 59872
March 26, 1976

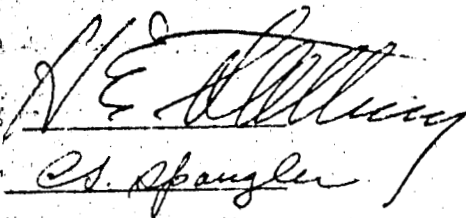
To whom it may concern in the Legislative Body in Helena,
Montana.

As Registered Pharmacists, we are against the repeal of the
substitution law, which is coming before the Legislative
Body in Helena, Montana.

Sincerely,

H.E. Stelling

C.S. Spangler

The block contains two handwritten signatures. The first signature, for H.E. Stelling, is written in dark ink and is a stylized, cursive representation of the name. The second signature, for C.S. Spangler, is also in dark ink and is a cursive signature. Both signatures are written over horizontal lines that serve as baselines for the typed names.

VALLEY DRUG

PRESCRIPTION DRUGS

VETERINARY SUPPLIES - COSMETICS - CARDS

STEVENSVILLE, MONTANA 59870

MAR 28, 1977

To whom it concerns,

I am against H.B. 286 which would allow free generic substitution of prescription drugs.

The PATIENT must be protected from the cheap & possibly lower quality of some of these generic drugs.

A good Doctor, - pharmacist, - patient relationship, which this bill could damage, allows the patient to receive the best drugs at the lowest cost.

Don Svenson RPh #2436
Stevensville
MT

INTERNAL CORRESPONDENCE



		from		
located		company	located	
		date		

THIS IS A LETTER AGAINST H.B. 286 - PALMER, ALLOWING A PHARMACIST TO SELECT A GENERICALLY, LOWER PRICED AND A BIOEQUIVALENT DRUG PRODUCT FOR A PURCHASER. THE DAs, ARE NOW WAITING GENERICALLY; SO THERE WOULD BE NO ADVANTAGE TO THIS BILL. AND BEING THAT THERE IS A DIFFERENCE IN THE MANUFACTURING AND INGREDIENTS OF GENERIC DRUGS - THE PATIENT WOULD BE THE ONE TO SUFFER THE SIDE EFFECTS FROM A DRUG THAT DOES NOT MEET THE REQUIREMENTS OF A BIOEQUIVALENT DRUG.

[Signature]

VALLEY DRUG
PRESCRIPTION DRUGS
VETERINARY SUPPLIES - COSMETICS - CARDS
STEVENSVILLE, MONTANA 59870

March 28, 1977.

To whom it concerns;

Let it be known that I am against HB 286 which calls for allowing random generic substitution of prescription drugs.

First of all, if the state is going to allow this, they should establish and fund a lab to assay the cheap "garbage" generics that are available.

Secondly this throws the full responsibility for drug selection upon the Pharmacist with the possibility of more lawsuits.

Alan E. Kelley, RPh
2203

A & C Drug

523 N. Higgins PAT HOLDEN Box 7966
~~127 EAST BROADWAY~~
MISSOULA, MONTANA 59801

To whom it may concern:

I, as a registered pharmacist, am opposed to Senate Bill # 286. This is for many of the reasons you have already heard plus, perhaps, one more. With the number of third party payments increasing each year the "can substitute" can very easily become "must substitute". This would, of course, be due to the reimbursement authorized by these third parties. I am sure that I as a pharmacist can carry quality drugs even with this bill up to the point where third parties start reimbursing for the lowest cost generic drug available. I am sure that you are already aware that generic equivalency does not necessarily guarantee chemical or medicinal equivalency.

Thank you for your time.

Sincerely,

Dennis Shanahan

Dennis Shanahan Reg. Pharm.
A & C Drug

A & C Drug

523 N. Higgins PAT HOLDEN
~~127 EAST BROADWAY~~ • P. O. BOX 1113
MISSOULA, MONTANA 59801

3/28/77

Senators on Public Health, Welfare and Safety
Senators
Capital Building
Helena, Montana

Dear Senators

I am strongly opposed to passage of HB 286.
There is no substitution for right and the
substitution of a generic drug is not the same

50



PHONE 542-0343

DRUG
STORE

P.O. BOX 1223

CORNER HIGGINS & BROADWAY MISSOULA MONTANA 59801

Senate Sub-committee Hearing on HB 286

Dear Sirs:

I would like to express my opposition to the substitution bill.
I fear the quality of our health care system will be sacrificed
for lower prices.

Sincerely,

Idelle Morgan



DRUG
STORE

PHONE 542-0343

P.O. BOX 1223

CORNER HIGGINS & BROADWAY MISSOULA MONTANA 59801

March 28, 1977

Senate Sub-committee Hearing on HB286

Dear Sirs:

I oppose this bill.

The entire issue is irrelevant because a pharmacist can, on request of the customer, and always has been able to dispense a less expensive generic equivalent simply by phoning the prescribing physician.

Quality is, to me, the most important ingredient in any prescription. There are several ways to determine quality: set up a chemical laboratory in the pharmacy and run comparative assays on different brands of a specific drug; research bioavailability monographs that have been compiled by other laboratories; or trust my knowledge of the companies who manufacture drug products. Obviously the first way is not feasible. Bioavailability data is not available for all drugs and it is important to note that the FDA, at least to date, has not established a bioequivalence requirement for any drugs. Therefore, I feel I must select pharmaceuticals from reliable pharmaceutical companies and not dispense a drug on the basis of its price.

I feel that if this bill passes, the day is in sight when I will be forced (esp. by 3rd parties) to dispense "cheap" instead of "quality".

Sincerely,

Nancy Manning
Nancy Manning RPh



DRUG
STORE

PHONE 542-0343

P.O. BOX 1223

CORNER HIGGINS & BROADWAY MISSOULA MONTANA 59801

March 25, 1977

Senate Sub-committee Hearing on HB 286:

Dear Sirs:

I am opposed to this bill for many reasons. The most important of which is that I feel this will be destructive of Clinical Research by which we have made so much progress in the last 20 years.

This bill is in direct opposition to the Federal Trade Mark Law and as such places us in an untenable position.

Sincerely,

Byron E. Dodd RPh

to Committee on Health, Education, And Safety.

to: House Bill 286 Drug Product Selection

Dear Sirs:

In this time where medicine has advanced to the point where the physicians are merely coordinators of a larger medical system and are losing their stronghold on total health care increasing pressure has been put on physicians to delegate out their power of product selection to the pharmacist. As a pharmacist I view this move with suspicion.

Proponents for repeal of anti-substitution point to consumer savings to the issue but study the cost.

Under present law a physician who works with a limited repertoire of drugs in his practice may specify one brand of a drug consistently and become familiarized with the results obtained. Allowing substitution interjects another variable into the already complex therapy scheme. While brand name alone does not assure quality it may contribute to uniformity of results.

Recently FDA reports have shown therapeutic inequivalence among so called bioequivalent drugs. Of the drugs involved, digoxin is a well documented example. Where the physician can not control the brand dispensed variation in absorption between brands can mean the difference between uncontrolled heart failure, controlled heart failure, and digoxin toxicity. Where a physician is familiar with the brands he prescribes he can better anticipate results.

Other proponents of the bill feel the pharmacist is more qualified to judge bioavailability data and select the product to be dispensed. While today's pharmacist does have training in evaluating bioequivalency data manufacturers have not made bioassay research widely available. In absence of this type of data we lack the one other thing that would enable us to judge products; results. The pharmacist is in a poor position to make any follow-up judgements of results, indeed the pharmacist often does not even the diagnosis of the disease being treated.

Realizing that bioinequivalence does exist, that bioavailability data is poorly disseminated, and that physicians can control uniformity of results through experience with drug brands I urge you to defeat the proposed repeal of the state's anti-substitution laws.

Sincerely,

Dale R. Wiseley
Dale R. Wiseley
R. Ph. 2661

East Gate Drug

BOX 1868 8121

EAST GATE SHOPPING CENTER

MISSOULA, MONTANA 59807

PHONE 549-5611



MARCH 28, 1977

SENATOR Wm. NORMAN M. D.
CAPITOL BLDG
HELENA, MONTANA 59601

DEAR DOCTOR NORMAN:

Re: HB 286

I AM AGAINST HB 286. IT NOT ONLY WILL NOT SAVE THE
PATIENT MONEY, BUT THERE IS EVERY POSSIBILITY THAT
IT WILL REDUCE THE QUALITY OF OUR MEDICAL CARE.

I AS A PHARMACIST WANT MY DOCTOR TO DETERMINE WHAT
IS BEST FOR ME, PLEASE NOT THE GOVERNMENT.

SINCERELY,

Don Whitman

DON WHITMAN RPH
EAST GATE DRUG CO
EAST GATE SHOPPING CENTER
MISSOULA, MONTANA

East Gate Drug

BOX 1266 8121

EAST GATE SHOPPING CENTER
MISSOULA, MONTANA 59807
PHONE 549-5611



MARCH 28, 1977

SENATOR Wm. NORMAN M. D.
CAPITOL BLDG.
HELENA, MONTANA 59601

DEAR DR. NORMAN:

Re: HB 286

I AM AGAINST HOUSE BILL 286. IT IS IMPOSSIBLE TO DISPENSE
THE LOWEST PRICED EQUIVELANT BECAUSE NOT ALL THE BIOAVAILABILTY
STUDIES ARE AVAILABLE TO US. THE BILL IS FULL OF HOLES AND I
THINK IT WILL LOWER MEDICAL STANDARDS.

THIS BILL SHOULD BE DEFEATED.

SINCERELY,

Jeannine O'Connor RPH

JEANNINE O'CONNOR RPH
EAST GATE DRUG

East Gate Drug

BOX 1228 8121

EAST GATE SHOPPING CENTER
MISSOULA, MONTANA 59801
PHONE 549-5611



MARCH 25, 1976

RE: HB 286

I HAVE NOT SEEN THE BILL SINCE IT WAS FIRST INTRODUCED. I UNDERSTAND IT HAS BEEN AMENDED. WITH THIS IN MIND, I CAN ONLY COMMENT GENERALLY, AND NOT ADDRESS THE SPECIFICS.

I THINK THE INTENT OF THIS BILL IS LAUDABLE. BASED ON MY PRACTICAL EXPERIENCE WORKING RELIEF IN MISSOULA, I CANNOT SEE THAT IT WOULD BRING ANY SIGNIFICANT CHANGE TO PRACTICES NOW BEING FOLLOWED. I WOULD HOPE THAT THE ELDERLY WOULD NOT BE MISLEAD INTO THINKING THERE WILL BE A GREAT REDUCTION IN THEIR PRESCRIPTIONS. MOST DOCTORS IN OUR COMMUNITY PRESCRIBE GENERICS WHEREVER POSSIBLE. I CAN'T SEE THAT THE BILL WOULD ACCOMPLISH MUCH MORE IN THE WAY OF SAVINGS. BUT THEN, I HAVEN'T READ THE BILL.

RESPECTFULLY,

Marriette D. Dooling, R. Ph.

57

PETERSON DRUG COMPANY

232 North Higgins Avenue
P. O. Box 1133
Missoula, Montana 59801

E. C. Kohlhaas, President

Phone: 549 2325

Missoula, Montana
March 20, 1977

Re: when it may concern:

We, the undersigned, oppose HB #286, the Product Selection Act. We do not feel that the pharmacist should be empowered with the selection of a substitute product without the consent of the prescribing practitioner. This choice should rest with the prescriber.

Harold C. Kohlhaas
Mont. #1364

David J. Hartwig, Rph.
Mont. #1909

Jack's Prescription Drive in Area
710 Orange St
3.26.77

Subject: Contona Drug Product Selection Act

Date: 3/26/77

Re: Oppose enactment of HB 286.

There are two major categories of prescription drugs in which generic drugs are widely available. One category is antibiotics and in this category the majority of prescriptions for antibiotics are currently being written generically. The pharmacists are filling these with major pharmaceutical manufacturers products, in other words, the pharmacist does not trust the dozens of cheap generic drug companies that do not identify their own product tablets as do the major drug firms. This indicates to me the generic drug company is in the business for the money, not for the benefit of the consumer or the pharmaceutical industry.

The other category is antihypertensive/diuretics & their combinations. In the second category the FDA has issued a list of 110 drugs where substitution is not advised due to bioequivalence problems. Twentyfive of the 110 are in this second category. This bill will have no beneficial effect because the bioequivalence problems pointed out by the FDA will prevent "drug product selection" in one or two major categories.

Also I quite frequently receive generic prescriptions for drugs that the FDA has labeled as having bioequivalence problems. This indicates the physicians writing these prescriptions to not realize the potential problems that may arise by using non-bioequivalent drugs.



SECOND AND HOSE STREETS
MISSOULA, MONTANA 59801
TELEPHONE: (406) 542-2191

D. A. WANBERG, ADMINISTRATOR

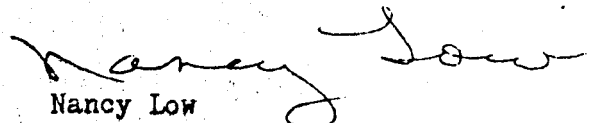
3-28-77

Senate Committee in charge of HB 286, Drug Substitution act,

As a registered Pharmacist I wish to go on record as being opposed to HB 286. It opens a can of legal worms. First it forces the Pharmacist to carry two inventories (which increases drug prices) & defeats the purpose. Second, the patient himself is not qualified or schooled in drugs to make that decision for himself. Thirdly, it leaves the door open for subpotent generics to find their way into Montana, if an unscrupulous Pharmacist wishes to do so.

There is really no need for this law as the Doctors are already free to ask for trade name or generic products now. Pharmacists co-operate with their wishes. Doctors have the medical training to be qualified in this area, the patient does not.

Thank you very much.


Nancy Low
Registered Pharmacist
2195

STOICK Pharmacies



PHONE (406) 543-4676

P.O. BOX 7339

MISSOULA, MONTANA 59807

March 28, 1977

Senate Committee on Public Health, Welfare and Safety
re: HB 286, The Montana Drug Product Selection Act

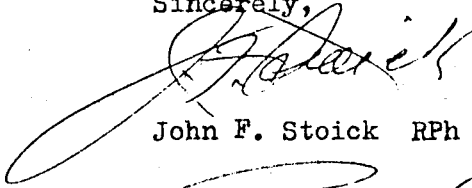
Senators,

We are opposed to HB 286 for many reasons, the following we feel are of key importance.

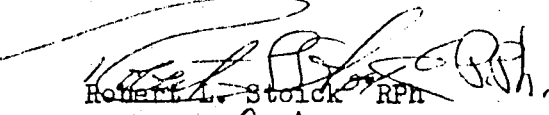
- 1) From the liability point of view. We are pharmacists, not prescribing physicians, and therefore should not be delegated the increased liability with which such a bill would burden us.
- 2) Consumer savings will be minimal regardless of what is expected by the proponents of this bill. Presently there are only about 20% of all pharmaceuticals produced that have generic equivalents. Competition in this area has become so strong that the majority of the manufactures have lowered prices in order to stay in the market.
- 3) Although FDA approved and supervised, the quality of many generic drugs and the credibility of their manufactures are questionable from our professional point of view.

We strongly urge your do not pass recommendation concerning this bill as we feel it will be a step further in the degradation of medical care in Montana and the United States.

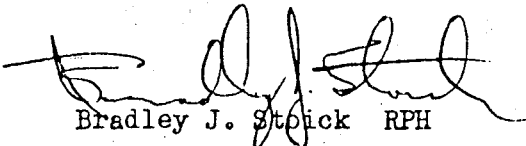
Sincerely,



John F. Stoick RPh



Robert L. Stoick RPh



Bradley J. Stoick RPh



DISCOUNT PHARMACY

Palmer M. Kronen - Owner

700 Southwest Higgins - Missoula, Montana 59801 - Phone 549-4125

3-28-77

Senate Committee

I'm apposed to house bill 286 as it is written, in many cases information on 'therapeutic equivalency' is not available to the pharmacist, and he hasn't the data to make proper judgment. Also making substitution of cheapest brand mandatory might not always be in the best interests of the patient.

Sincerely,

A handwritten signature in cursive script, reading "Palmer M. Kronen". The signature is written in dark ink and is positioned below the "Sincerely," text.



March 29, 1977

Senate Public Health Committee
Capitol Building
Helena, Montana 59601

Dear Sirs:

Re: HB #286- which would allow pharmacists to select a less expensive generic drug product.

In keeping with quality medical care, why would we want to use the least expensive brand available, rather than brands of much better quality?

If there were printed some type of compendia which would list which products are actually bioequivalent, it would be much easier to make this sort of product selection. As it is now, how do we know that one brand of erythromycin stearate is equivalent in every way to a less expensive brand of erythromycin stearate.

It is my opinion at this time, that Pharmacists today are delivering the patient the best products available, and at the most reasonably priced. If the patient wants a generic substitution made now, all that it requires is a phone call to the Dr. The patient may also ask the M.D. to write the prescription generically, originally.

For these reasons, I cannot support HB # 286.

Sincerely,

G.M. Stocking
G.M. Stocking, R.Ph.

J.W. Moody
J.W. Moody, R.Ph.

STATEMENT BY L. BRINN

*Salvatore
Lator Lake*

The facts and figures I am about to give are partly from documented evidence and partly from personal experience. My remarks regarding generic substitution may seem prejudiced, however after 22 years in the armed forces, over half of it as a Pharmacy Technician, I became somewhat bitter at the devious means any conscientious pharmacy personnel had to use to elude dispensing the obviously inferior products that were purchased at seemingly bargain prices or to put it bluntly 'the lowest price got the bid'.

It is ironic that several years ago Pharmacists seemed to enjoy selling the higher priced medications, though they made a smaller percentage on the transaction, there was a good dollar volume. Now it seems that some Pharmacists, not necessarily the majority, are promoting the lower priced entities. Odd, isn't it?

I shall at this time present a few excerpts from some of the documented evidence I am submitting. Each committee member will receive a copy of the evidence. Time does not permit me to present this in its entirety.

Alfred Gilman Ph.D., co-author of Goodman & Gilman, the most widely used Pharmacology book in teaching institutions, in an open letter to Sen. Gaylord Nelson, which incidentally may be found in the Congressional Record of Sept. 12, 1967 states: "I am appalled by many of those statements which imply that generic drugs, marketed cheaply by small drug companies, are the equivalent of established trademarked preparations merely because chemical analysis indicates that the preparation actually contains the specified amount of drug."
..."I have seen instances where slight changes in formulation have doubled the blood levels and halved the therapeutic dose of the drug. These were not clinical impressions but carefully designed and accurate studies. I am, therefore, convinced that there is not such a thing as a generic equivalent unless proven by adequate experimental data."

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MINUTES OF THE MEETING

PUBLIC HEALTH, WELFARE AND SAFETY COMMITTEE

March 31, 1977

The thirty-seventh meeting of the Public Health, Welfare and Safety Committee was called to order by Chairman Stephens in Room 405 of the State Capitol Building on the above date at approximately 5:15 P.M.

ROLL CALL: All members of the Committee were present.

EXECUTIVE SESSION for work on the following bills - (all House bills) 455, 658, 772, 286, and 627.

ACTION ON HOUSE BILLS 455: With no discussion, Senator Roberts moved HB455 BE CONCURRED IN - 7 voted yes (1 Senator late and missed vote). (Senator Roberts will carry on Floor.)

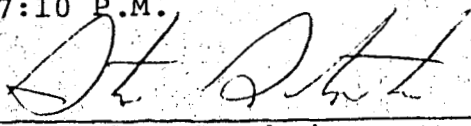
ACTION ON HOUSE BILL 658: After a short discussion, Senator Rasmussen moved BE CONCURRED IN - 5 voted yes, 2 no, 1 absent on the vote. (Senator Norman will carry on Floor.)

ACTION ON HOUSE BILL 772: This bill was held up for a few days until the Subcommittee could report back to the whole Committee. Following Senator Norman's report, Senator Norman moved HB772, AS AMENDED, BE CONCURRED IN - unanimous vote yes. (Senator Watt will carry.)

ACTION ON HOUSE BILL 286: This generic drug bill demanded a lot of attention from Committee members - long testimony was given at a prior hearing. Senator Norman gave the Committee direction in trying to amend the bill to the Committee's satisfaction so that a vote could be taken. Lobbyists for Montana State Pharmaceutical Association and Montana Medical Association were on hand to answer more questions. Senators Olson, Norman, and Rasmussen gave the Committee the benefit of their years of service as doctors. Senator Rasmussen made the observation that the V.A. has substituted generic drugs for years. Senators Norman, Roberts and Watt moved the various amendments the Committee adopted (See Standing Committee Report). Senator Watt then moved HB286, AS AMENDED, BE CONCURRED IN - on a tie vote of 4-4, bill was reported out of Committee WITHOUT RECOMMENDATION. (Senator Watt will carry on Senate Floor.)

ANNOUNCEMENTS: Chairman Stephens asked the Committee to wait until Tuesday, April 5, to take action on HB627 because of its complexity.

ADJOURNMENT: With no further business at this time, Chairman Stephens adjourned the meeting at 7:10 P.M.


STAN STEPHENS, Chairman

ROLL CALL

VOTE

SENATE COMMITTEE PUBLIC HEALTH, WELFARE AND SAFETY

45th LEGISLATIVE SESSION - 1977.

Date 3/31 Bill No. HB 386 Time

NAME S:	YES	NO
LEE, Robert	✓	
RASMUSSEN, Tom	2	
OLSON, Stuart		1
HIMSL, Matt		2
WATT, Robert	3	
ROBERTS, Joe		3
NORMAN, Bill - V. Chm.	(4)	
STEPHENS, Stan - Chairman		(4)

Joyce (Kelly) Allen
Secretary

STAN STEPHENS
Chairman

Motion: Senator Watt moves
As Amended, Be Concurred In
Without Recommendation

STANDING COMMITTEE REPORT

APRIL 1

19 77

MR. PRESIDENT

We, your committee on PUBLIC HEALTH, WELFARE AND SAFETY

having had under consideration HOUSE Bill No. 236

Respectfully report as follows: That HOUSE Bill No. 286

third reading bill, be amended as follows:

1. Amend page 3, section 3, line 6.

Following: "select"

Strike: "an equally priced or"

Insert: "a"

2. Amend page 3, section 3, line 17.

Following: "patient."

Strike: "An example of an acceptable certification would be the notation "medically necessary" or words of similar meaning on the face of a written prescription. In no case may a facsimile of the handwritten signature be preprinted to indicate "medically necessary."

~~XXXX~~
DO PASS

(MORE)

STATE PUB. CO.
Helena, Mont.

STAN STEPHENS,

Chairman.

68

April 1, 1977

3. Amend page 4, section 5, line 17.

Following: "Section 3."

Strike: lines 17 through 20 in their entirety.

Insert: "Savings passed on." (1) A pharmacist selecting a less expensive drug product must pass on to the purchaser the full amount of the savings realized by the product selection. In no event may the pharmacist charge a different professional fee for dispensing a different drug product than the drug product originally prescribed."

4. Amend page 5, section 6, lines 6 through 9.

Following: line 5

Strike: Section 6 in its entirety.

Renumber: subsequent sections.

5. Amend page 12, section 11, line 6.

Following: "specifies"

Strike: ", except as provided in the Montana Drug Product Selection Act."

END, AS SO AMENDED, WITHOUT RECOMMENDATION.

STAN STEPHENS, Chairman

April 4, 1977

SENATE
COMMITTEE OF THE WHOLE

That House Bill No. 286, third reading, be amended as follows:

1. Amend page 2, section 1, line 8.

Following: line 7

Insert: "(6) Person means an individual, firm, partnership, association, corporation, or any other entity, whether organized for profit or not."

Renumber: all subsequent subsections

2. Amend page 3, section 3, line 15.

Following: "certifying"

Strike: "in his own handwriting"

3. Amend page 4, section 4, lines 3 and 4.

Following: "prescription"

Strike: "of the product selection"

4. Amend page 4, section 4, line 13.

Following: "which is"

Strike: "therapeutically"

HOUSE BILL NO. 286

INTRODUCED BY PALMER, HANSEN, KESSLER, COONEY

A BILL FOR AN ACT ENTITLED: "AN ACT TO BE CALLED THE MONTANA DRUG PRODUCT SELECTION ACT, ALLOWING FOR PRODUCT SELECTION OF CERTAIN PRESCRIBED DRUGS; AMENDING SECTIONS 27-703 AND 66-1523, R.C.M. 1947."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Short title. This act may be cited as the "Montana Drug Product Selection Act".

Section 2. Definitions. As used in this act the following definitions apply:

(1) "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

(2) "Bioequivalent" means a chemical equivalent which, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

(3) "Brand name" means the proprietary or the registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.

REFERENCE BILL

(4) "Chemical equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendium standards.

(5) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

(6) PERSON MEANS AN INDIVIDUAL, FIRM, PARTNERSHIP, ASSOCIATION, CORPORATION, OR ANY OTHER ENTITY, WHETHER ORGANIZED FOR PROFIT OR NOT.

~~(6)~~(7) "Generic name" means the chemical or established name of a drug product or drug ingredients published in the latest edition of the official United States Pharmacopoeia or official Homeopathic Pharmacopoeia of the United States.

~~(7)~~(8) "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia and the National Formulary.

~~(8)~~(9) "Prescriber" means a practitioner licensed under the professional laws of the state to administer medicine and drugs.

~~(9)~~(10) "Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.

1 ~~(107)(111)~~ "Therapeutically equivalent" means those
2 chemical equivalents which, when administered in the same
3 dosage regimen, will provide essentially the same
4 therapeutic effect as measured by the control of a symptom
5 or a disease and/or toxicity.

6 Section 3. Product selection permitted. (1) Except as
7 limited by subsection (2) of this section and unless
8 instructed otherwise by the purchaser, the pharmacist who
9 receives a written or oral prescription for a specific drug
10 product by brand or proprietary name may select ~~on--equally~~
11 ~~priced--or~~ A less expensive drug product with the same
12 generic name, the same strength, quantity, dose, and dosage
13 form as the prescribed drug which is, in the pharmacist's
14 professional opinion, therapeutically equivalent,
15 BIOEQUIVALENT, AND BIOAVAILABLE.

16 (2) If, in the professional opinion of the prescriber,
17 it is medically necessary for his patient that an equivalent
18 drug product not be selected, the prescriber may so indicate
19 by certifying ~~in--his--own--handwriting~~ that in his
20 professional judgment the specific brand name drug product
21 is medically necessary for that particular patient. ~~An~~
22 ~~example-of-an-acceptable-certification-would-be-the-notation~~
23 ~~"medically-necessary"-or-words-of-similar-meaning-on-the~~
24 ~~face-of-a-written-prescription--in-no-case-may-a-facsimile~~
25 ~~of-the-handwritten-signature-be-preprinted-to-indicate~~

1 ~~"medically-necessary".~~ In the case of a prescription
2 transmitted orally, the prescriber must expressly indicate
3 to the pharmacist that the brand name drug product
4 prescribed is medically necessary.

5 Section 4. Notice to purchaser. (1) A pharmacist who
6 selects a drug product as provided in [section 3] shall
7 notify the person presenting the prescription ~~of-the-product~~
8 ~~selection, together-with-the-existence--and--amount--of--the~~
9 ~~retail--price-difference-between-the-brand-name-drug-product~~
10 ~~and-the-drug-product-substituted-for-it-and-shall-inform-the~~
11 ~~person-presenting-the-prescription~~ that he may refuse the
12 product selection as provided in [section 3].

13 (2) Each pharmacy shall display in a prominent place
14 that is in clear and unobstructed public view, at or near
15 the place where prescriptions are dispensed, a sign stating,
16 "This pharmacy may be able to select a less expensive drug
17 product which is ~~therapeutically~~ equivalent to the one
18 prescribed by your physician unless you or your physician
19 request otherwise." The printing on the sign shall be in
20 block letters not less than 1 inch in height.

21 Section 5. ~~Product-selection-when-no-increased-costs~~
22 ~~(1)--A-pharmacist-may-select-a-drug-product-under--[section~~
23 ~~3]-only-when-there-will-be-a-savings-or-no-increased-cost-to~~
24 ~~the-purchaser.~~

25 SAVINGS PASSED ON. (1) A PHARMACIST SELECTING A LESS

1 EXPENSIVE DRUG PRODUCT MUST PASS ON TO THE PURCHASER THE
 2 FULL AMOUNT OF THE SAVINGS REALIZED BY THE PRODUCT
 3 SELECTION. IN NO EVENT MAY THE PHARMACIST CHARGE A DIFFERENT
 4 PROFESSIONAL FEE FOR DISPENSING A DIFFERENT DRUG PRODUCT
 5 THAN THE DRUG PRODUCT ORIGINALLY PRESCRIBED.

6 ~~{2}--A pharmacist selecting a less expensive drug~~
 7 ~~product must pass on to the purchaser the full amount of the~~
 8 ~~savings realized by the product selections. In no event may~~
 9 ~~the pharmacist charge a different professional fee for~~
 10 ~~dispensing a different drug product than the drug product~~
 11 ~~originally prescribed.~~

12 ~~{3}~~(2) If the prescriber prescribes a drug product by
 13 its generic name, the pharmacist must, consistent with
 14 reasonable judgment, dispense the lowest retail priced,
 15 therapeutically equivalent brand which is in stock.

16 ~~Section 6--Records required and labeling--(1)--Each~~
 17 ~~pharmacist shall maintain a record of any product selection~~
 18 ~~of a generically equivalent drug product for a prescribed~~
 19 ~~brand name drug product as provided for in this act.~~

20 ~~{2}--Except as provided in subsection (3) of this~~
 21 ~~section, when a pharmacist dispenses a selected drug product~~
 22 ~~as authorized, he must label the prescription container with~~
 23 ~~the name of the dispensed drug product. If the dispensed~~
 24 ~~drug product does not have a brand name, the prescription~~
 25 ~~label must indicate the generic name of the drug product~~

1 ~~dispensed along with the name of the drug product's~~
 2 ~~manufacturer.~~

3 ~~{3}--Unless the prescriber writes "do not label" or~~
 4 ~~words of similar meaning on the prescription or so~~
 5 ~~designates in an oral transmission of the prescription, a~~
 6 ~~prescription dispensed by a pharmacist must bear upon the~~
 7 ~~label the name of the medication in the container.~~

8 Section 6. Product selection not practice of medicine.
 9 The selection of a drug product by a registered pharmacist
 10 under the provisions of this act does not constitute the
 11 practice of medicine.

12 Section 7. When product selection evidence of
 13 negligence. (1) A pharmacist making a product selection
 14 under the provisions of this act assumes no greater
 15 responsibility for selecting the dispensed drug product than
 16 he would incur in filling a prescription for a drug product
 17 prescribed by a generic name.

18 (2) ~~In no event when~~ WHEN a pharmacist selects a drug
 19 product ~~with~~ the prescriber be MAY NOT BE HELD liable in an
 20 action for loss, damage, injury, or death to a person caused
 21 by the use of the selected drug product ~~unless the original~~
 22 ~~drug product was incorrectly prescribed.~~ EXCEPT THAT IF THE
 23 ORIGINAL DRUG PRODUCT WAS INCORRECTLY PRESCRIBED, THE
 24 PRESCRIBER IS NOT RELIEVED OF LIABILITY.

25 Section 8. Rule making authorized. The board of

1 pharmacists may adopt, amend, or repeal rules necessary for
2 the implementation, continuation, and enforcement of this
3 act in accordance with the Montana Administrative Procedure
4 Act.

5 Section 9. Section 27-703, R.C.M. 1947, is amended to
6 read as follows:

7 "27-703. Prohibited acts enumerated. The following
8 acts and the causing thereof within the state of Montana are
9 hereby prohibited:

10 (a)(1) The manufacture, sale or delivery, holding or
11 offering for sale of any food, drug, device, or cosmetic
12 that is adulterated or misbranded.

13 (b)(2) The adulteration or misbranding of any food,
14 drug, device, or cosmetic.

15 (c)(3) The receipt in commerce of any food, drug,
16 device, or cosmetic that is adulterated or misbranded, and
17 the delivery or proffered delivery thereof for pay or
18 otherwise.

19 (d)(4) The sale, delivery for sale, holding for sale,
20 or offering for sale of any article in violation of section
21 27-712 or 27-717.

22 (e)(5) The dissemination of any false advertisement.

23 (f)(6) The refusal to permit entry or inspection or to
24 permit the taking of a sample, as authorized by section
25 27-722.

1 (g)(7) The giving of a guaranty or undertaking which
2 guaranty or undertaking is false, except by a person who
3 relied on a guaranty or undertaking to the same effect
4 (effect) signed by, and containing the name and address of
5 the person residing in the state of Montana from whom he
6 received in good faith the food, drug, device, or cosmetic.

7 (h)(8) The removal or disposal of a detained or
8 embargoed article in violation of section 27-706.

9 (i)(9) The alteration, mutilation, destruction,
10 obliteration, or removal of the whole or any part of the
11 labeling of, or the doing of any other act with respect to a
12 food, drug, device, or cosmetic, if such act is done while
13 such article is held for sale and results in such article
14 being adulterated or misbranded.

15 (j)(10) Forging, counterfeiting, simulating, or falsely
16 representing, or, without proper authority, using any mark,
17 stamp, tag, label, or other identification device authorized
18 or required by regulations promulgated under the provisions
19 of this act or of the ~~Federal Act~~ federal act.

20 (k)(11) The using, on the labeling of any drug or in
21 any advertisement relating to such drug, of any
22 representation or suggestion that an application with
23 respect to such drug is effective under section 27-717, or
24 that such drug complies with the provisions of such section.

25 (l)(12) In the case of a prescription drug distributed

1 or offered for sale in this state, the failure of the
 2 manufacturer, packer, or distributor thereof to maintain for
 3 transmittal, or to transmit, to any practitioner licensed by
 4 applicable law to administer such drug who makes written
 5 request for information as to such drug, true and correct
 6 copies of all printed matter which is required to be
 7 included in any package in which that drug is distributed or
 8 sold, or such other printed matter as is approved under the
 9 Federal Act federal act. Nothing in this paragraph shall be
 10 construed to exempt any person from any labeling requirement
 11 imposed by or under other provisions of this act.

12 ~~f1)(13)~~ (Counterfeiting trade-marks).

13 ~~f1)(a)~~ Placing or causing to be placed upon any drug
 14 or device or container thereof, with intent to defraud, the
 15 trade name or other identifying mark, or imprint of another
 16 or any likeness of any of the foregoing; or

17 ~~f2)(b)~~ Selling, dispensing, disposing of, or causing
 18 to be sold, dispensed, or disposed of or concealing or
 19 keeping in possession, control, or custody, with intent to
 20 sell, dispense, or dispose of, any drug, device, or any
 21 container thereof, with knowledge that the trade name or
 22 other identifying mark or imprint of another or any likeness
 23 of any of the foregoing has been placed thereon in a manner
 24 prohibited by subsection ~~f1)(a)~~ hereof; or

25 ~~f3)(c)~~ Making, selling, disposing of, or causing to be

1 made, sold, or disposed of or keeping in possession,
 2 control, or custody, or concealing, with intent to defraud,
 3 any punch, die, plate, or other thing designed to print,
 4 imprint, or reproduce that trade name or other identifying
 5 mark or imprint of another or any likeness of any of the
 6 foregoing upon any drug, device, or container thereof.

7 ~~f4)(n) Dispensing or causing to be dispensed a different~~
 8 ~~drug or brand of drug in place of the drug or brand of drug~~
 9 ~~ordered or prescribed without the express permission in each~~
 10 ~~case of the person ordering or prescribing.~~

11 ~~f4)(14)~~ The using by any person to his own advantage
 12 or revealing, other than to the state board, or officers or
 13 employees of the department, or to the courts when relevant
 14 in any judicial proceeding under this act, any information
 15 acquired under authority of this act concerning any method
 16 or process which as a trade secret is entitled to
 17 protection.

18 ~~f4)(15)~~ The distribution in commerce of a consumer
 19 commodity, as defined in this act, if such commodity is
 20 contained in a package, or if there is affixed to that
 21 commodity a label, which does not conform to the provisions
 22 of this act and of regulations promulgated under authority
 23 of this act, ~~provided, however, that this~~ This prohibition
 24 ~~shall not~~ does not apply to persons engaged in business as
 25 wholesale or retail distributors of consumer commodities

1 except to the extent that such persons:

2 ~~†††(a)~~ are engaged in the packaging or labeling of

3 such commodities; ~~†~~ or

4 ~~†††(b)~~ prescribe or specify by any means the manner in

5 which such commodities are packaged or labeled.

6 ~~†††(16)~~ The labeling or packaging of a food, drug, or

7 cosmetic which fails to conform with the requirements of

8 this act.

9 ~~†††(17)~~ It is unlawful for any person to sell or offer

10 for sale any product which is in semblance of honey and

11 which is labeled, advertised, or otherwise represented to be

12 honey, if it is not honey. Any product sold in semblance of

13 honey which is a blend or mixture of honey and other

14 ingredients must be labeled in such a way that the name of

15 the main ingredient added to the honey will be printed so

16 that it will be as prominent and conspicuous as the word

17 honey. The word "imitation" ~~shall~~ may not be used in the

18 name of a product which is in semblance of honey whether or

19 not it contains any honey. The label for a product which is

20 not in semblance of honey and which contains honey may

21 include the word "honey" in the name of the product, and the

22 relative position of the word "honey" in the product name,

23 and in the list of ingredients, when required, shall be

24 determined by its prominence as an ingredient in the

25 product."

1 Section 10. Section 66-1523, R.C.M. 1947, is amended

2 to read as follows:

3 "66-1523. Wrongful labeling. (1) It ~~shall--be~~ is

4 unlawful for any person who prepares prescriptions, drugs,

5 medicines, chemicals, ~~or poisons willfully~~ to purposefully

6 ~~or negligently~~ or ignorantly to omit to label the package

7 or receptacle, ~~or label it falsely--substitute--an--article~~

8 ~~different from the one ordered or deviate in any manner from~~

9 ~~the requirements of an order or prescription.~~

10 (2) No person may substitute a drug different from the

11 one ordered or deviate in any manner from the requirements

12 of an order or prescription, except as provided in the

13 Montana Drug Product Selection Act.

14 ~~†††(3)~~ On prescription drugs, the label shall contain

15 the name and strength of the drug, unless the prescriber

16 otherwise specifies, ~~except as provided in the Montana Drug~~

17 ~~Product Selection Act."~~

18 Section 11. Penalties. (1) In addition to all other

19 penalties provided by law, a person who violates the

20 provisions of [sections 3, 4, or 5] or any rule promulgated

21 as provided in [section 9] shall be fined no more than \$250

22 for each violation.

23 (2) The penalty imposed under this act may be remitted

24 or mitigated upon such terms and conditions as the board of

25 pharmacists considers proper and consistent with the public

1 health and safety.

2 (3) A civil penalty imposed under this act becomes due
3 and payable when the person incurring the penalty receives a
4 notice in writing from the board of pharmacists. The notice
5 shall be sent by registered or certified mail and must
6 include:

7 (a) reference to the particular sections of the
8 statute or rule;

9 (b) a short and plain statement of the matters
10 asserted as charged;

11 (c) a statement of the amount of the penalty or
12 penalties imposed; and

13 (d) a statement of the person's right to request a
14 hearing.

15 (4) The person to whom the notice is addressed has 20
16 days from the date of the notice in which to make written
17 application for a hearing before the board of pharmacists.

18 Section 12. Severability. If a part of this act is
19 invalid, all valid parts that are severable from the invalid
20 part remain in effect. If a part of this act is invalid in
21 one or more of its applications, the part remains in effect
22 in all valid applications that are severable from the
23 invalid applications.

-End-